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THAT WONDERFUL YEAR: SMALLPOX, GENETIC ENGINEERING, AND BIO-TERRORISM

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In retrospect, 1973 was a most remarkable year. In January, the Miami Dolphins won Super Bowl VII, capping the only undefeated season in National Football League history;[1] through the spring, Secretariat, perhaps the greatest thoroughbred ever, swept horse racing's Triple Crown;[2] and in September, Billy Jean King whipped Bobby Riggs in tennis's much-hyped "Battle of the Sexes."[3] More seriously, 1973 was the year of the Supreme Court's famous *Roe v. Wade*[4] decision on abortion; Chile's President Salvador Allende Gossens was ousted and assassinated in a military *coup d'etat*;[5] the disastrous Yom Kippur war erupted between Israel and its neighbors;[6] and a cease fire agreement brought U.S. disengagement from Vietnam and the return of the first American prisoners of war.[7] In addition, of course, the year was thoroughly dominated by the televised spectacle of the Senate Watergate hearings,[8] the "Saturday Night Massacre" of Special Prosecutor Archibald Cox,[9] and the resignations, indictments, and convictions of the perpetrators of the infamous "third rate burglary."[10]

Hidden beneath the glare of those most luminous events, 1973 has also proven—with the benefit of three decades of hindsight—to

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1. *Year by Year Results*, USA TODAY, Feb. 4, 2002, at 10C.
2. AMERICAN DECADES: 1970-1979, at 505 (Victor Bondi ed., 1995).
3. *Id.*
4. 410 U.S. 113 (1973).
5. AMERICAN DECADES 1970-1979, *supra* note 2, at 9.
6. *Id.* (noting that on October 6, 1973, war erupted between Israel and its neighbors Egypt and Syria).
7. *Id.* at 220.
8. *See id.* at 220-22 (tracing the development of the Watergate scandal throughout 1973); *Richard Milhous Nixon: 1913-1994, Key Events in the Life of the 37th President*, ATLANTA J. & CONST., Apr. 23, 1994, at A11.
9. Jack Torry, *Watergate 30 Years Later; The Scandal that Changed the Nation*, COLUMBUS DISPATCH, June 16, 2002, at A1.
10. *Id.* In another ominous harbinger of some of the issues addressed in this Article, 1973 also witnessed two lethal terrorist attacks upon European airports. The first, in August, killed three and injured fifty-five in Athens. AMERICAN DECADES 1970-1979, *supra* note 2, at 9. The second, in December, killed thirty-one in Rome. *Id.* at 10. On a more personal note, 1973 was also a watershed year for the author: I became engaged to my wonderful wife, Karen, and I graduated from college that year.

be a watershed year in three other important, seemingly unrelated areas of public policy: biochemistry, public health, and arms control. Now, in the early days of the twenty-first century, these three areas have combined in unforeseen ways to offer the promise of dramatic advances in human health and well-being, but simultaneously threaten the very foundations of global peace and security.

The three sectors—biochemistry, public health, and arms control—were revolutionized in 1973 in ways that even the principal actors of the day could barely begin to appreciate. First, that year brought the dawn of the miracle of genetic engineering when California biochemists Herbert W. Boyer and Stanley N. Cohen succeeded for the first time in transferring a snippet of DNA between creatures of unrelated species.[11] They developed a technique for deftly slicing a genetic fragment from the ribosome of an African clawed frog Xenopus laevis and splicing it into a chromosome of the bacterium Escherichia coli. They witnessed the world's first genetically-altered creature, which proceeded to function with both sets of hereditary instructions.[12] The succeeding years, of course, have greatly refined the techniques and expanded the range of recombinant creatures that can be created and manipulated in this way, leading to breathtaking success (but also considerable dangers, as well as arcane ethical quandaries) in pharmacology, agriculture, and other far-flung applications.[13]

Second, 1973 marked an unmistakable milestone in the global campaign against the dread disease smallpox[14]—previously responsible for millions of needless deaths each year.[15] In that year, the World Health Organization (WHO), the driving force in mankind's grand struggle to eradicate the planet's most devastating illness, reinvigo-

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11. Stanley N. Cohen, *The Manipulation of Genes*, SCI. AM., July 1975, at 25, 31 (reporting in detail the history and scientific processes behind cutting strands of DNA and importing them into other organisms).

12. *See id.* at 31 (providing a description of the events at the Stanford laboratories from the perspective of one of the key researchers).

13. *See generally* PAUL BERG & MAXINE SINGER, DEALING WITH GENES: THE LANGUAGE OF HEREDITY 221-38 (1992) (exploring the use of recombinant DNA technology in genetic engineering of plants and animals); Sarah Crawford Martinelli, *Genetic Engineering, in* 1 ENCYCLOPEDIA OF GENETICS 243-49 (Jeffrey A. Knight ed., 1999) (describing key discoveries in the field of genetic engineering).

14. *See* FRANK FENNER ET AL., SMALLPOX AND ITS ERADICATION 495, 503 (1988) (identifying 1973 as "a year of hope" when global eradication seemed attainable).

15. Lawrence K. Altman et al., *Smallpox: The Once and Future Scourge?*, N.Y. TIMES, June 15, 1999, at F1 (reporting that smallpox caused up to half a billion deaths in the twentieth century).

rated its Intensified Smallpox Eradication Programme.[16] The WHO was able in 1973 to certify the complete elimination of smallpox from the Western Hemisphere, and to concentrate its full administrative, financial, and personnel resources on only six countries where the stubborn disease remained endemic.[17] Although 135,904 cases were still reported in 1973,[18] the WHO's objective, a global "Target Zero,"[19] at last appeared within reach, and in just four more years it was finally realized.[20] The triumph over smallpox—the first disease ever completely eradicated from the human population[21]—remains the crowning achievement of the WHO and of public health officials around the world and provides the template for the ongoing campaigns against polio, measles, and other noxious impairments.[22]

Finally, and purely coincidentally, 1973 also witnessed a remarkable development in international security, as previously-bickering countries finally united behind the Biological Weapons Convention (BWC),[23] the first arms control agreement to accomplish a measure of genuine disarmament—the total removal of an entire category of lethal weaponry from national arsenals around the world.[24] The treaty had been signed in grand fashion in 1972, but it was subject to ratifica-

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16. *See* FENNER ET AL., *supra* note 14, at 530 (detailing the intensified efforts of the WHO that began in 1973).

17. *Id.* The remaining six countries were India, Bangladesh, Pakistan, Ethiopia, Botswana, and Nepal. *Id.*

18. *Id.*

19. *Id.* at 530.

20. *Id.* at 536 (stating that smallpox was finally eradicated in October, 1977).

21. *See* David Brown, *Campaign to Eradicate Polio Is Near an End, Officials Say*, WASH. POST, Apr. 17, 2002, at A2.

22. *See id.* (reporting that the WHO's effort to eliminate polio, building upon the model of the smallpox success, has reduced occurrences to only ten countries, which reported 537 cases in 2001); UNICEF, A WORLD WITHOUT POLIO (observing that by the end of 2002, polio was endemic in only seven countries worldwide), *at* www.unicef.org/polio (last visited Mar. 27, 2003); WORLD HEALTH ORG., DISEASE ERADICATION OR ELIMINATION (identifying several other diseases that the WHO is on the threshold of eliminating in the same way as it did smallpox, including leprosy, guinea worm disease, and chagas disease), *at* www.who.int/archives/who50/en/elimination.htm (last visited Mar. 27, 2003).

23. Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *opened for signature* Apr. 10, 1972, 26 U.S.T. 583, 1015 U.N.T.S. 163 [hereinafter Biological Weapons Convention].

24. *See id.* at 585-86, 1015 U.N.T.S. at 164-66 (articulating the goals of the BWC); *see also* Charles C. Flowerree, *Chemical and Biological Weapons and Arms Control*, *in* ENCYCLOPEDIA OF ARMS CONTROL AND DISARMAMENT 999, 1006 (Richard Dean Burns ed., 1993) (noting that the "[United States] confirmed that the entire U.S. stockpile had been destroyed and [biological-warfare] facilities [had been converted to peaceful] purposes" on March 4, 1975).

tion by all participating countries before it could enter into force[25]—a process that in many instances requires years of delicate diplomatic maneuvering. In the case of the BWC, however, the timetable was vividly compressed: the necessary number of countries rushed to deposit their instruments of ratification in 1973, paving the way for formal legal acceptance of the document two years later.[26] While the life of the BWC has not always been smooth,[27] its swift ascent in 1973 was most impressive, providing a solid initial basis for the legal regime[28] and a model for later accords on chemical weapons, conventional forces, and other armaments.[29]

This Article undertakes to weave together those three seemingly disparate strands into a single coherent story—one that concludes with the world today confronting an unprecedented danger of biological terrorism. In 2003, as the world celebrates a quarter century of freedom from the ancient scourge of smallpox, and as we contemplate the final eradication of the insidious virus that caused that loathsome disease, we simultaneously face the specter that this noxious little bug, a hardy, complex, and near-unique virus known as variola, may once again be unleashed upon an unsuspecting and largely unprepared public. Worse yet, a genetically modified variant of the virus, perhaps created and housed in secrecy for years in Soviet/Russian or other rogue facilities, may lurk on the horizon, capable of evading whatever modest defenses modern medicine has managed to create to battle the natural versions of the creature.

25. The BWC was opened for signature on April 10, 1972; and it specified that it would enter into force upon ratification by twenty-two countries, including the United States, the Soviet Union, and the United Kingdom, who were designated as depositaries for the treaty. Biological Weapons Convention, *supra* note 23, 26 U.S.T. at 591-92, 1015 U.N.T.S. at 168.

26. Eight signatories deposited their instruments in 1972, nineteen in 1973, six in 1974, and twenty-six (including the three depositaries simultaneously) in 1975. U.S. ARMS CONTROL AND DISARMAMENT AGENCY, ARMS CONTROL AND DISARMAMENT AGREEMENTS: TEXTS AND HISTORIES OF NEGOTIATIONS 128-31 (1982) [hereinafter ACDA TREATY BOOK]. Entry into force occurred on March 26, 1975. *Id.* at 124.

27. *See infra* notes 227-257 and accompanying text (discussing the development of the BWC and recent American opposition to attempts to enhance its provisions).

28. *See* Flowerree, *supra* note 24, at 1006 (observing that the immediate responses of the BWC member countries to the treaty's provisions were encouraging). Prior to entry into force of the BWC, the United States and the United Kingdom were in complete compliance with its provisions and the Soviets asserted that they were making progress. *Id.* In 1978, the U.N. General Assembly gave an unreserved, favorable report on the BWC. *Id.*

29. *Id.* at 1011-14 (describing international efforts to regulate chemical weapons after adoption of the BWC); *see also* ACDA TREATY BOOK, *supra* note 26, at 137-99 (providing descriptions of several treaties negotiated after the BWC, limiting anti-ballistic missiles, intercontinental ballistic missiles, chemical weapons, environmental modification techniques, and other arms).

The thesis of this Article is that the United States, Russia, and by extension, the world as a whole, are pursuing a fundamentally sound strategy in retaining, rather than destroying, the last known remaining samples of the variola virus. For now, those samples are housed in secure, deep-freeze storage at the U.S. Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia[30] and at the comparable Russian facility, known as Vector,[31] near Novosibirsk, Siberia. But that basic decision is about the only correct move we are making at this time—and even it is animated by fundamental misapprehensions about the stakes and the long-term strategy.[32] Instead of undertaking a crash program of smallpox-related research, as demanded by the Bush administration,[33] and instead of manufacturing and possibly administering hundreds of millions of doses of anti-smallpox vaccines, we would be well-advised to turn our attention and our resources elsewhere.[34] We should preserve the virus, despite insistent pressure from most countries in the WHO to destroy it, but we should mostly confine it to continued long-term storage while we proceed judiciously in pursuit of other biological, public health, and national security opportunities first identified in 1973.[35]

This Article unfolds in five steps. First, it explores the centuries-old saga of smallpox, revealing how the disease has ravaged populations around the planet and left a trail of unmitigated human death and suffering. At the same time, the human struggle against, and ultimately our collective triumph over, smallpox provides one of the most stirring stories of human industry, collegiality, resourcefulness, and panache. By eradicating the disease and subduing the causative virus, human beings have imposed their will on a recalcitrant segment of nature and have done so with unalloyed virtue. Even as we celebrate that triumph, however, we worry that our collective guard has been let

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30. FENNER ET AL., *supra* note 14, at 1341.

31. World Health Organization, Report by the Director-General, Communicable Disease Prevention and Control: Smallpox Eradication: Destruction of Variola Virus Stocks, EB97/14 (1995) (formally designating the facilities of Vector to be a WHO collaborating center and variola repository).

32. *See infra* notes 523-537 and accompanying text (outlining the steps the United States should take in response to the current threat of biological warfare including a reprioritization of our financial resources dedicated to research and prevention, as well as diplomatic maneuvers that may help address the threat).

33. *See infra* notes 508-511 and accompanying text (articulating a more restrained approach to variola research).

34. *See infra* notes 490-502 and accompanying text (suggesting several other avenues the United States should pursue instead of overstocking the current vaccine).

35. *See infra* notes 486-537 and accompanying text (illustrating several ways the United States can combat biological weapons through advances in other areas of domestic and foreign policy).

down, perhaps exposing us once again to the predations of the disease, and we recognize the unfinished business on the global agenda: do we now destroy the virus, conduct additional experiments upon it, or retain it indefinitely?

The second part of the Article examines the security dimension of the issue, recounting how smallpox was one of the handful of biological agents that has been regularly considered, occasionally developed and stockpiled, and episodically used as a tool of warfare and terrorism. Societies across the millennia have repeatedly sought to marry the cellular secrets of the life sciences with the battlefield secrets of the military sciences;[36] a string of treaties has only partially reined in this rapacious instinct.[37] Certainly, illnesses like smallpox—deliberately induced or erratically encountered as part of the misfortunes of war—have exerted a dominant influence in military matters through history, swinging the tide of battles, tilting the outcome of wars, and triggering the rise and fall of empires. Today, the leading legal prohibition against biological warfare, the BWC, is under unprecedented stress as its inherent shortcomings in the areas of verification and enforcement,[38] and its inadequacies in dealing with the onslaught of modern super-terrorism, are fully exposed. Unfortunately, it has been the United States that has shamefully led the resistance to diplomatic efforts to ameliorate the problems.[39]

Third, the Article presents a lay person's introduction to genetic engineering, especially the intricate ways in which the most sophisticated DNA manipulations now open the door for deft reformation of the genetic legacy of creatures from bacteria to sheep to human beings. The danger that the viral genome may be manipulated in similar fashion—to render variola even more deadly and impervious to

36. *See infra* notes 191-207 and accompanying text (describing some of the inventive methods armies have used to infect their enemies).

37. *See infra* notes 208-232 and accompanying text (discussing the historical progression of treaties designed to curtail the use of biological weapons).

38. Currently, the BWC does not have an inspection arm to verify compliance with the convention. *See* THOMAS GRAHAM JR., DISARMAMENT SKETCHES: THREE DECADES OF ARMS CONTROL AND INTERNATIONAL LAW 29 (2002) (asserting that while "Articles V, VI, and VII of the BWC provide the verification mechanism . . . in essence, the BWC has no verification provisions at all"); Jeremy Feiler, *U.S. to Focus on Biosecurity, Legal Issues at November BWC Meeting*, INSIDE THE PENTAGON, Jan. 30, 2003, 2003 WL 8752179 (discussing the United States' agenda for the November 2002 BWC meeting as well as its opposition to previous verification proposals).

39. In an effort to protect domestic biotechnology companies from possible industrial espionage and to safeguard classified defense programs, the United States has rejected BWC proposals. Feiler, *supra* note 38 (citing an unnamed U.S. government official); *see also* GRAHAM, *supra* note 38, at 30 (noting U.S. biotech industry opposition to the development of a verification protocol for the BWC).

our defenses—is horrifying. Even worse is the possibility that it may already have happened, as defectors from the Soviet enterprise claim.[40] The invocation of a biological warfare "chimera," an agent that genetically combines the most lethal aspects of variola, Ebola, or other incurable pathogens, is a scenario we must now confront.[41]

The fourth part of the Article pulls those distinct disciplines together, summarizing how the world has so far responded to this rapidly evolving thicket of threats. It surveys the misadventures by the WHO; the American and Russian resistance to the drumbeat in favor of destroying the last variola samples; and the spasmodic reaction to the terrorist onslaughts of September and October 2001—including the procurement of vast quantities of an old, highly-successful, but still problematic anti-smallpox vaccine.

Finally, the Article offers recommendations for a revised future course. Various legal tools are surveyed including treaty amendment, codification of public health statutes, upgrading national and international scientific research facilities, and enhancement of international cooperation. All of this is done in the effort to develop augmented physical health and national safety. As we seek to apply the lessons of 1973 to the circumstances of 2003, we must draw upon all our resources to avoid the horrors of smallpox biological terrorism.

I. THE ANCIENT SCOURGE OF SMALLPOX

No other infectious disease has afflicted human beings with more death, suffering, fear, and revulsion, over a longer period of time, and with a wider geographic coverage than smallpox.[42] The virus killed twenty to thirty percent of the people it infected, there was no cure, and it was so readily transmitted between individuals that a perpetual supply of fresh victims was assured.[43] Those who somehow managed to survive were generally left with disfiguring scars and were fre-

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40. *See infra* notes 346-348 and accompanying text (discussing the claims of a Russian defector regarding the development of a dangerous viral "chimera").

41. *See infra* notes 337-355 and accompanying text (describing potential military applications of modern biological weapons).

42. Nicolau Barquet & Pere Domingo, *Smallpox: The Triumph over the Most Terrible of the Ministers of Death*, 127 ANNALS INTERNAL MED. 635, 635 (1997).

43. *See* FENNER ET AL., *supra* note 14, at 3-4 (stating that smallpox "was regarded as a uniformly severe disease, associated with a high case fatality rate, in every part of the world"); Abbas M. Behbehani, *Smallpox*, *in* 4 ENCYCLOPEDIA OF MICROBIOLOGY 33 (Joshua Lederberg ed., 1992) (explaining that smallpox "killed more people than any other infectious disease"); Donald A. Henderson et al., *Smallpox as a Biological Weapon: Medical and Public Health Management*, 281 JAMA 2127, 2127-28 (1999) (stating that smallpox admits no specific therapy, it has a mortality rate of 30%, and prior to vaccinations almost everyone contracted the disease).

quently blinded.[44] It has been estimated that over a run of years in many countries, fully ten percent of all human deaths each year were attributable to this single cause.[45] In the twentieth century alone, perhaps 500 million people were felled by variola virus.[46]

A. *Smallpox Through History*

No one knows when or where smallpox originated; some speculate that variola may have emerged near the Ganges River in India around 10,000 B.C. as a mutation from some earlier animal-infecting microorganism.[47] Inspection of three Egyptian mummies from 1570 to 1085 B.C. has uncovered evidence of ancient smallpox. Pharoh Ramses V, who died in 1157 B.C. carries the distinction of being the first individually identified smallpox victim.[48] Other antiquarian empires—the Hittites, Athenians, Carthaginians, and Romans among them—have handed down records reflecting devastating diseases that may have been smallpox, and societies from India to China to sub-Saharan Africa also struggled unsuccessfully with variola through the centuries.[49]

The roster of prominent smallpox victims reads like an historic *Who's Who.* Queen Elizabeth I of England, King Louis XIV of France, George Washington, and Abraham Lincoln each somehow survived the disease, but so many others were less fortunate.[50] As physician-

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Significantly less lethal versions of the smallpox virus also came into existence: Variola minor killed only approximately 1% of its victims, and Variola intermedius was fatal about 12% of the time. FENNER ET AL., *supra,* at 3-4, 38-40, 242-43; DONALD R. HOPKINS, PRINCES AND PEASANTS: SMALLPOX IN HISTORY 6 (1983). These strains are quite similar genetically, and no one knows how the different types evolved. *Id.* at 287. Variola minor became much more common than Variola major in the United States and certain other regions during the twentieth century. The markedly reduced severity of this version of smallpox led some communities to take smallpox much less seriously than those afflicted primarily by the most virulent Variola major. *See id.* at 287-90.

44. FENNER ET AL., *supra* note 14, at 49-50, 135, 1117-18; *see also* HOPKINS, *supra* note 43, at 5 (describing how permanent blindness occurred in approximately 1% of the cases). Smallpox lesions usually appeared first on the face, and permanent scarring, found in 65-80% of the survivors, was usually heaviest there. FENNER ET AL., *supra,* at 49.

45. E. WAGNER STEARN & ALLEN E. STEARN, THE EFFECT OF SMALLPOX ON THE DESTINY OF THE AMERINDIAN 135 (1998); *see also* FENNER ET AL., *supra* note 14, at 715 (describing how smallpox caused 13% of all recorded deaths in Calcutta, India).

46. Altman et al., *supra* note 15.

47. *See* HOPKINS, *supra* note 43, at 13 (speculating that the virus emerged in agricultural settlements in Asia or Africa about 10,000 B.C.).

48. *Id.* at 14.

49. *See generally* FENNER ET AL., *supra* note 14, at 210-17 (surveying global smallpox experience prior to 1000 A.D.); HOPKINS, *supra* note 43, at 16-21, 103-24 (discussing probable evidence of smallpox in the Hittite Empire, India, and China).

50. HOPKINS, *supra* note 43, at 1-3, 36, 258, 277-81.

epidemiologist Donald R. Hopkins reports, smallpox assassinated "a queen of England, an Austrian emperor, a king of Spain, a tsar of Russia, a queen of Sweden, and a king of France in the eighty years before 1775."[51] Of course, the disease ravaged the common people and anonymous children too. In some cultures, smallpox was such a frequent killer of infants "that custom forbade the naming of a newborn until the infant had caught the disease and proved it would survive."[52]

B. *The Disease Process*

The disease progression in a standard case[53] began with a ten- to fourteen-day incubation or latency period, following which the first symptoms (headache, backache, fever, chills, and convulsions) would appear.[54] Then, oddly, for a day or two, the victim would feel better, and the fever would subside as if some other, less deadly ailment had been the cause.[55] After that, however, the smallpox infection aggravated: a rash would erupt, and spread over the face, arms, chest, back, and legs; the rash would rise into pimples, blisters, and then pustules; and these would eventually dry into scabs or crusts.[56] The victim's skin turned pink or red, felt hot to the touch, and might peel off in limp sheets.[57] While those external signs were intensifying, the internal developments were even worse. The virus would infest the lungs, liver, heart, and other organs, causing hemorrhaging and toxemia.[58] Opportunistic bacteria could invade the skin lesions, generating an additional source of infection.[59] Death might occur within a few days

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51. *Id.* at 41; *see also* Michael Radetsky, *Smallpox: A History of Its Rise and Fall*, PEDIATRIC INFECTIOUS DISEASE J., Feb. 1999, at 85, 85 (citing other historical figures killed by smallpox).

52. WORLD HEALTH ORG., WHO FACT SHEET ON SMALLPOX (2001), *at* http://www.who.int/emc/diseases/smallpox/factsheet.html (last visited Mar. 28, 2003).

53. Several distinct types of smallpox illness were identified, characterized by different arrays of fever, pustules, internal organ damage, and fatality rates. FENNER ET AL., *supra* note 14, at 4-38. These came to be categorized as hemorrhagic, malignant, confluent, flat, and other types. *Id.*

54. *See id.* at 5-6, 188 (describing symptoms such as headaches, backaches, and convulsions); HOPKINS, *supra* note 43, at 3-4; WORLD HEALTH ORG., *supra* note 52, *at* http://www.who.int/emc/diseases/smallpox/factsheet.html (listing fever, headache, severe back pain, and vomiting as among the symptoms of smallpox).

55. HOPKINS, *supra* note 43, at 4 (describing the end of the prodromal stage during which the victim temporarily felt better).

56. *Id.*

57. *Id.* at 4; *see also* FENNER ET AL., *supra* note 14, at 19-21 (describing skin lesion progression and rash distribution).

58. HOPKINS, *supra* note 43, at 4-5.

59. *Id.* at 5.

after the onset of the most vivid symptoms, or the victim might linger for days or weeks.[60]

The smallpox virus remained communicable for up to three weeks, and the disease was readily spread to surrounding persons.[61] Each sneeze or exhaled breath could propel millions of infectious viruses into the atmosphere, where they could linger for days before wafting into someone else's inhalations.[62] The scabs contained infectious pus too, and the victim's clothing, linens, or shroud often served as vehicles for transmitting the virus to succeeding generations of sufferers.[63] Up to half the people exposed to the virus could contract the illness.[64]

Three key characteristics shaped the patterns of smallpox transmission and marked humans' interactions with the virus. First, smallpox was a once-in-a-lifetime event. Anyone who contracted the disease and somehow survived it was probably permanently immune from any subsequent re-infection by variola.[65] Second, the virus is human-specific; there is no reservoir for variola to lie dormant in plants, animals, or the environment, as there is for so many other pathogens.[66] Third, the disease manifests in an acute, highly-detectable form. There are no asymptomatic carriers who might spread the disease without knowing it.[67]

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60. *Id.* at 4-5.

61. *See* FENNER ET AL., *supra* note 14, at 189-90 (discussing contamination through direct contact with a victim's skin, scabs, or bedsheets); HOPKINS, *supra* note 43, at 3 (discussing infection through face-to-face contact).

62. FENNER ET AL., *supra* note 14, at 123-24, 182-88, 191-94. The variola virus can persist for lengthy periods in a favorable environment. *See id.* at 115 (describing how samples of the virus remained viable for thirteen years when stored in an envelope in a laboratory cupboard).

63. *Id.* at 185-86, 189-94. Transmission of variola virus usually depended upon close physical contact with an infected person or his or her personal effects. HOPKINS, *supra* note 43, at 3. Because infected persons were usually too ill to travel or work, smallpox was not routinely communicated through public markets, schools or job sites; instead, family members and hospitals became the primary conduits for transmitting the disease throughout the community. *See* FENNER ET AL., *supra*, at 68, 189, 201-03 (citing epidemics in Glasgow in 1950 and Yugoslavia in 1972, as characteristic of this pattern); WORLD HEALTH ORG., *supra* note 52, *at* http://www.who.int/emc/diseases/smallpox/factsheet.html.

64. *See* HOPKINS, *supra* note 43, at 3 (stating that a susceptible person who shared a household with a smallpox victim had a 50% chance of being infected).

65. *See* FENNER ET AL., *supra* note 14, at 51-52, 146-47 (describing one study that observed one repeat attack in one thousand cases at an average interval of fifteen to twenty years).

66. *Id.* at 96, 479-80, 1333.

67. *Id.* at 190. Subclinical infection by variola was unusual and epidemiologically unimportant, although some types of smallpox did not manifest the usual array of pox eruptions. *Id.* at 208.

As a result of these factors, smallpox traditionally appeared in waves, several years apart.[68] It might flare in a particular city, when it was introduced by an infected visitor from abroad, and rampage through the local population until most people in the community were either killed or rendered immune by surviving the attack. Thereafter, there might be no local smallpox cases for several years, until a new generation of unexposed children was born and the virus was once again haphazardly introduced.[69] Accordingly, in many locations, smallpox became an episodic illness of children. In eighteenth century Britain, for example, ninety percent of the victims were under ten years old.[70]

C. *Treatment for Smallpox*

There was, and still is, no cure or specific treatment for smallpox.[71] Desperate people through the ages invented all manner of medical regimens for combating the disease, building upon the then-prevailing sense of medical arts. Some prayed to a variety of smallpox-designated deities;[72] some practiced bleeding the body of excessive humors;[73] some (over-reacting to the color of the smallpox rash) applied "red treatment" by surrounding the victim with red sheets, curtains, and implements, and supplying him or her only red food and drink.[74] For several centuries, the leading routine in many countries was "heat therapy," which consisted of confining the victim in warm clothes and huddling him or her around a fire.[75] Later, that routine

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68. *Id.* at 178; *see also id.* at 227, 230 (charting the cyclical peaks and valleys in smallpox fatalities in the Hida district on Honshe Island, Japan, and in London).

Smallpox could be sustained as *endemic*—always locally present and subject to occasional flare-ups—in a relatively populous area. HOPKINS, *supra* note 43, at 8. Some calculated that a minimum population of 200,000 would be required to incubate variola in this way. FENNER ET AL., *supra* note 14, at 118. In smaller towns, in contrast, the virus would appear, cause a temporary epidemic, and then fade away until a sufficiently large vulnerable group had been born and the virus re-introduced. HOPKINS, *supra* note 43, at 8.

69. HOPKINS, *supra* note 43, at 8.

70. Behbehani, *supra* note 43, at 34; *see also* HOPKINS, *supra* note 43, at 52 (stating that most children born in eighteenth century London had the disease before they reached the age of seven).

71. WORLD HEALTH ORG., *supra* note 52, *at* http://www.who.int/emc/diseases/smallpox/factsheet.html.

72. *See* HOPKINS, *supra* note 43, at 135-38, 159-63, 200-03 (discussing various cultures' gods and goddesses of smallpox).

73. *Id.* at 11-12; *see also id.* at 295 (describing different treatment regimens for smallpox from diverse societies throughout history, including purgatives, liniments, special diets, and Spartan or environmentally pure lifestyles).

74. FENNER ET AL., *supra* note 14, at 228; HOPKINS, *supra* note 43, at 295-300.

75. HOPKINS, *supra* note 43, at 27; Radetsky, *supra* note 51, at 86. The dominant approach to smallpox in Europe during the Middle Ages was shaped by the contributions of

was abruptly inverted by others who favored a cooling treatment, but had no better results.[76] Modern post-exposure protocols are no more promising. Even in the twentieth century, smallpox patients were afforded little more than sympathetic and skilled nursing care, pain control, symptom relief, avoidance of secondary infection, and quarantine.[77]

D. *Vaccination*

Instead, the most efficacious method for dealing with smallpox was to avoid contracting the disease in the first place.[78] To that end, the world's first vaccine against any disease was developed by the inquisitive English country doctor, Edward Jenner, who observed that dairymaids who had previously been infected with a mild skin disease known as cowpox thereafter seemed immune to smallpox.[79] After me-

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Baghdad physician Rhazes (850-925), whose work, *A Treatise on the Small-Pox and Measles*, introduced the concepts that those two illnesses were distinct entities, and that "heat treatment" or "sweat therapy" provided the appropriate regimen for smallpox. HOPKINS, *supra* note 43, at 27. That remained the prevailing medical view in much of the world for seven centuries until England's Thomas Sydenham reversed the customary wisdom by 180 degrees and promulgated "cooling treatment," featuring open windows and lighter bed coverings, in the mid-1600s. *Id.* at 33. It was Sydenham who noted the partially iatrogenic nature of the high fatality rates for smallpox, observing that wealthy victims, who could afford the "best" available treatment routines, died of smallpox at greater rates than did the poor. *Id.*

76. HOPKINS, *supra* note 43, at 33.

77. FENNER ET AL., *supra* note 14, at 68.

78. An important alternative strategy, known as variolation or inoculation, involved precisely the opposite approach. Under it, a person would deliberately incur a relatively minor case of smallpox and hope that the disease could be managed at the non-fatal level, thereby establishing lifetime immunity to subsequent exposures. *Id.* at 245-46. Variolation proceeded in different ways in different countries. Sometimes a dried powder derived from smallpox skin crusts harvested from a current victim was inhaled by others. *Id.* at 252. In other cases, a quantity of pus from a smallpox lesion was injected into a cut on the arm of the person to be protected. *Id.* at 253; HOPKINS, *supra* note 43, at 46. Variolation had been practiced in Africa, China, and elsewhere for centuries, and it was famously introduced into Europe by Lady Mary Wortley Montague, the wife of the British ambassador to the Ottoman Empire, and into America by the Reverend Cotton Mather, both in 1721. FENNER ET AL., *supra* note 14, at 252-58; HOPKINS, *supra* note 43, at 47-48, 248.

Ordinarily, a person who acquired smallpox artificially in this way would suffer reduced symptoms and had only a 1-2% chance of dying. However, he or she was still fully infectious and could pass full-strength smallpox to anyone nearby. FENNER ET AL., *supra* note 14, at 246. Therefore, while some saw variolation as a viable technique for reducing the danger of incipient smallpox epidemics, others argued that the methodology served more often to initiate a new chain of disease transmission. *Id.* at 255-56. In some communities, the practice of variolation persisted well into the twentieth century. *Id.* at 253 (citing the common practice of variolation in Afghanistan and parts of Pakistan through the 1970s).

79. Others had made the same observation and had occasionally attempted to validate cowpox as an anti-smallpox treatment, but Jenner was the first to study in detail the con-

ticulous empirical observation, Jenner conducted his famous experiment in 1796 by injecting eight-year-old James Phipps with infectious cowpox material. When the boy recovered from that transient illness, Jenner attempted—unsuccessfully—to infect him with smallpox.[80]

Jenner's insights revolutionized the world's struggles against smallpox.[81] Within only a few years, the technique, and the precious cowpox infective materials, had proliferated throughout the world.[82] Thomas Jefferson, for example, quickly became an enthusiastic convert, vaccinating his own family and groups of visiting Indian chiefs.[83] As the innovative therapy saved millions from the predations of the disease, Jefferson enthusiastically wrote to Jenner, "You have erased from the calendar of human afflictions one of its greatest. Yours is the comfortable reflection that mankind can never forget that you have lived. Future nations will know by history only that the loathsome smallpox has existed."[84]

E. *Limitations upon Vaccination*

Jefferson's praise notwithstanding, vaccination did not prove to be quite the panacea its enthusiasts had contemplated.[85] First, it did not provide life-long immunity, as surviving a bout of smallpox did. After exposure to cowpox, which is now recognized as being a closely-

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nection between the two illnesses, to undertake empirical surveys, and to publicize the results. FENNER ET AL., *supra* note 14, at 258-61; HOPKINS, *supra* note 43, at 77-81.

80. FENNER ET AL., *supra* note 14, at 258-61; HOPKINS, *supra* note 43, at 79. Jenner's experiment did not draw immediate, universal acceptance, but before long, the efficacy of the new procedure became manifest, and the process spread rapidly. FENNER ET AL., *supra* note 14, at 263-67, 271-73; HOPKINS, *supra*, at 81-86.

81. *See* FENNER ET AL., *supra* note 14, at 261-63 (observing that vaccination was taken up with remarkable alacrity throughout Europe and the United States, and it paid immediate dividends by dramatically increasing average life expectancy).

Jenner coined the term "vaccination" from the Latin word "*vacca*," for cow. *Id.* at 292. In homage to the 1796 accomplishment, Louis Pasteur in 1881 generalized the use of the word, so that "vaccination" now applies to all sorts of immunizing injections against a wide range of diseases. *Id.*

82. *Id.* at 261-63; HOPKINS, *supra* note 43, at 262-67. King Carlos IV of Spain was especially prominent in the global dispersion of vaccination, promulgating the practice in Spain's New World colonies. *Id.* at 223-25.

83. HOPKINS, *supra* note 43, at 265.

84. *Id.* at 310 (quoting Jefferson's 1806 letter to Jenner).

85. An important subsidiary mystery about smallpox must be noted. Although Jenner's original vaccination was accomplished with the cowpox virus, the material used for this purpose in modern times is not cowpox virus, but another related virus known as vaccinia, which itself might be a polyglot creature, perhaps evolving from cowpox, horsepox, or other sources. *See* FENNER ET AL., *supra* note 14, at 74, 278. No one now knows how this transformation occurred. Sometime in the 200 years since Jenner's discovery, the conversion from cowpox to vaccinia as an anti-smallpox prophylactic was somehow completely universal, inadvertent, and invisible to practitioners. *Id.*

related cousin of variola,[86] both members of the orthopox virus genus, protection seems to wane erratically.[87] No definitive studies were conducted, but it appears that the immunity was most robust for only a decade or so, after which a re-vaccination would be necessary.[88]

Second, there were side effects from vaccination. These were minor for most people, but quite problematic, or even life-threatening, for some.[89] Cowpox was generally a relatively benign virus, but for certain categories of people, it was strongly contraindicated. Those who suffered from eczema or related skin anomalies; pregnant women; people with certain disorders of the central nervous system; and more importantly today, people whose immune systems were suppressed by cancer treatments or by diseases such as AIDS were all high risk for vaccinia.[90] Careful statistics were not collected in the early years, but today it appears that of every one million vaccinations, approximately 1-2 people would be expected to die from untreatable complications; another 14-52 would suffer life-threatening reactions; and 49-935 other people would experience serious, but not critical effects.[91] Moreover, vaccinia virus was itself communicable: anyone

86. *Id.* at 72-73.

87. *Id.* at 278.

88. Jenner always insisted that proper vaccination would confer permanent immunity to smallpox. *Id.* at 260. However, experience soon demonstrated that the protection would degrade depending upon the strain of vaccine used, the vaccination procedure, the person's age at vaccination, the person's genetic resistance to disease, and other idiosyncratic factors. *Id.* at 42-43. For most people, vaccination provided robust protection for at least five years, but by the twenty-year point, there was little residual immunity. *Id.* at 42-43; WORLD HEALTH ORG., *supra* note 52, *at* http://www.who.int/emc/diseases/smallpox/factsheet.html. *But see* Jon Cohen, *Smallpox Vaccinations: How Much Protection Remains?*, 294 SCI. 985, 985 (2001) (citing a 1996 study, which demonstrated that some immunity in response to smallpox vaccination may persist for up to fifty years). Even an old vaccination might help reduce the severity of any smallpox that was incurred. FENNER ET AL., *supra* note 14, at 42-44, 52-53; Cohen, *supra*, at 985; WORLD HEALTH ORG., *supra*, *at* http://www.who.int/emc/diseases/smallpox/factsheet.html. Pox researchers and others at special risk were routinely re-vaccinated every three years. Even today, uncertainty persists regarding the durability of the immunity conferred by vaccination, and there is no way to obtain reliable data. Cohen, *supra*, at 985.

89. FENNER ET AL., *supra* note 14, at 296-306 (stating that post-vaccination symptoms include lesions and post-vaccinal encephalitis).

90. *Id.* at 299-302; *see also* Steven R. Rosenthal et al., *Developing New Smallpox Vaccines*, 7 EMERGING INFECTIOUS DISEASES 920, 921 (2001) (discussing the risks of vaccination for persons who are immunodeficient or pregnant).

91. Richard W. Stevenson & Sheryl Gay Stolberg, *Threats and Responses: Vaccinations; Bush Lays Out Plan on Smallpox Shots; Military Is First*, N.Y. TIMES, Dec. 14, 2002, at A1 (reporting the opinion of Dr. Anthony S. Fauci, director of the National Institute for Allergy and Infectious Diseases). *But see* Laura MacInnis, *Smallpox Shot Safer for Those Already Immunized*, REUTERS HEALTH, Dec. 24, 2002 (suggesting that vaccinia would be appreciably safer for adults who were immunized against smallpox years ago as children and would probably be more able to tolerate a second vaccination now).

who encountered a recently-vaccinated person would be in danger of acquiring the potentially problematic infection too.[92]

Third, the methods used to produce the vaccine were, when judged by modern standards, quite primitive, running the risk that the injection would expose the recipient to other, unwanted infections in addition to cowpox. The standard mechanism for generating the vaccine—harvesting cowpox materials from scarified calf tissues—would inevitably collect other miscellaneous impurities and germs too.[93] Likewise, some of the early routines for dispensing the vaccine, such as passing cowpox via serial arm-to-arm injections, could convey other infections as well.[94]

Finally, as with any new medical technology, there were practical considerations: the cost of vaccination placed the treatment out of reach of many, especially in poor communities and countries. Many early practitioners, not really understanding the biochemistry of their procedures, were incompetent in administering the vaccine, had acquired non-viable strains to work with, or were blatantly dishonest. Moreover, logistical difficulties—producing mass quantities of vaccine, transporting it to areas of need, preserving it adequately, and training people to administer it effectively and safely—often impeded lifesaving efforts.[95] As a result, the progression toward a smallpox-free world was halting and irregular.

F. Modern Smallpox Outbreaks

Through the nineteenth century, three major epidemics rocked even the most developed European countries, and the economically disadvantaged majority of the world had obtained only slight relief from Jenner's innovation.[96] Even into the twentieth century, small-

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92. Kent A. Sepkowitz, *How Contagious Is Vaccinia?*, 348 NEW ENG. J. MED. 439, 442-43 (2003) (describing reports of the spread of vaccinia virus within families as well as other inadvertent infectious occurrences).

93. FENNER ET AL., *supra* note 14, at 265-67, 279-81, 551-54; Rosenthal et al., *supra* note 90, at 920.

94. HOPKINS, *supra* note 43, at 85 (describing the transmission of vaccinia-syphilis to forty-four of sixty-three children vaccinated with material taken from one infant with an inapparent syphilis infection). Arm-to-arm vaccination was finally banned in Great Britain in 1898. FENNER ET AL., *supra* note 14, at 266.

95. HOPKINS, *supra* note 43, at 264-68, 274 (noting the difficulties in obtaining adequate supplies of potent vaccinia virus in nineteenth century America); JONATHAN B. TUCKER, SCOURGE: THE ONCE AND FUTURE THREAT OF SMALLPOX 28-29 (2001) (describing King Carlos IV of Spain's attempt at delivering the vaccine to North and South America by employing a living chain of cowpox carriers recruited from local orphanages).

96. *See* FENNER ET AL., *supra* note 14, at 272-73 (discussing smallpox epidemics in Europe that were especially severe in 1824-1829, 1837-1840, and 1870-1871); HOPKINS, *supra*

pox persisted as a global scourge: it was endemic in 124 countries in 1920.[97] Russia lost over 400,000 people to the disease in 1900-1909;[98] outbreaks of a relatively mild form of smallpox in the United States afflicted 135,000 in 1901-1902 and another 200,000 in 1920-1921.[99]

The post-World War II period amplified the disease's economic discrimination. Because of comprehensive national vaccination programs, smallpox was essentially eradicated in the United States in 1949[100] and in most of Europe (despite occasional reintroductions of the disease, imported by travelers from Africa and Asia).[101] Into the 1950s, however, there were probably as many as fifty million smallpox cases per year in the developing world.[102] As late as 1967, smallpox was still reported in thirty-one countries, most of them poverty-stricken, and there may have been as many as ten to fifteen million cases, with some two million deaths, annually.[103]

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note 43, at 86-96, 124-31, 147-54 (examining nineteenth century smallpox outbreaks in Europe, East Asia, and India).

97. *See* FENNER ET AL., *supra* note 14, at 171-72 (explaining that in 1920, smallpox was absent in Oceania and had been eliminated in Europe only in Denmark, the Netherlands, Norway, and Sweden).

98. *Id.* at 321 (depicting numbers of reported smallpox deaths in selected European countries between 1900 and 1919).

99. HOPKINS, *supra* note 43, at 290-91. The dominant form of smallpox in the United States in the twentieth century was Variola minor, which carried a greatly reduced risk of death. Partly as a result, the United States was relatively reluctant to adopt mandatory vaccination policies, and the American population experienced lower rates of smallpox protection than those of most other developed countries. *Id.* at 290-92.

100. No smallpox cases were reported in the United States between 1929 and 1946, when the disease was re-introduced by a soldier returning from Japan to Seattle, sparking an outbreak of 51 cases that caused 16 deaths. FENNER ET AL., *supra* note 14, at 330-31. In 1947, a man died from smallpox in New York City, and 12 other people were infected, triggering the immediate vaccination of six million people. *Id.* at 331-32. The last incidence of smallpox in the United States, with 8 cases and 1 death, occurred in Texas in 1949. *Id.* at 332 (noting that the case was likely imported from Mexico).

101. The ease of international travel facilitated frequent importations of the disease into European countries where endemic smallpox had been eradicated. *Id.* at 1070. There were 34 re-introductions of smallpox into Europe between 1959 and 1974, producing 573 cases, including 90 fatalities. *Id.* at 1074. In the most famous instance, a religious pilgrim returning from Mecca was infected with smallpox in Baghdad. *Id.* at 1091-92. When he arrived home to the Kosovo province in Yugoslavia in March 1972, he triggered an outbreak of 175 cases, including 35 deaths. *Id.* at 1094.

102. *See* TUCKER, *supra* note 95, at 63 (asserting that "the true magnitude of the problem was unknown: Widespread nonreporting and underreporting of cases had created a huge gap between the official statistics and reality").

103. FENNER ET AL., *supra* note 14, at 517-19, 1363; TUCKER, *supra* note 95, at 63.

G. *World Health Organization Actions*

In response to this heartbreaking toll, the WHO (the relevant "specialized agency" of the United Nations)[104] rose haltingly, and perhaps somewhat reluctantly,[105] to the occasion. It launched an Intensified Smallpox Eradication Programme (ISEP) in 1967, with an ambitious ten-year time horizon for complete global eradication of the disease.[106] A mélange of diverse factors promoted success: modest amounts of money (the total cost of the enterprise came to approximately $300 million);[107] a small, but preternaturally skilled and dedi-

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104. The World Health Organization was created by treaty in 1948 and quickly concluded a formal relationship agreement with the United Nations, becoming the parent institution for global cooperation in the wide array of health-related activities. *See* PEACE BY PIECES—UNITED NATIONS AGENCIES AND THEIR ROLES: A READER AND SELECTIVE BIBLIOGRAPHY 5 (Robert N. Wells, Jr. ed., 1991). Today, the WHO is one of the largest of the sixteen United Nations specialized agencies, with 191 states as members and an annual budget of approximately $1 billion. 1 WORLDMARK ENCYCLOPEDIA OF THE NATIONS: THE UNITED NATIONS 241-54 (10th ed. 2001). It has become the leading international authority regarding smallpox eradication and the primary forum within which decisions about destruction of the variola virus have been taken. *Id.* at 246.

105. The WHO and others had previously attempted to eradicate other notorious global diseases, such as yellow fever and malaria, but those efforts had always foundered due to shortages of funding, discord over priorities, and lack of institutional skills or resources. FENNER ET AL., *supra* note 14, at 388-89. Even with smallpox, some countries disputed whether greater attention should be devoted to other diseases, and some in the WHO leadership remained skeptical that complete eradication would ever be achievable, that member countries could be persuaded to dedicate sufficient resources to the effort, or that the organization should commit itself so fully to that single overarching goal. *Id.* The WHO's first foray into the field, the 1959 launching of a Smallpox Eradication Program, soon sputtered; in 1967, advocates succeeded in "intensifying" that effort, and in injecting renewed energy and funding. *Id.* at 365-419.

106. World Health Assembly, Res. 20.15, *Smallpox Eradication Programme* (May 17, 1967). In fact, the last smallpox case was recorded in Somalia ten years, nine months, and twenty-six days after the adoption of the ISEP objective. FENNER ET AL., *supra* note 14, at 538 (stating that the World Health Assembly formally declared on May 8, 1980 that smallpox had been eradicated).

107. FENNER ET AL., *supra* note 14, at 1365. The original proposals projected that global eradication of smallpox could be accomplished for $180 million, of which about 30% would come from international sources, including WHO and voluntary donations. *Id.* at 413. The initial WHO allocation for the smallpox campaign, a $2.4 million fund, was approved by the World Health Assembly in 1966 by only two votes—the closest margin for adopting a budget in the organization's history. *Id.* at 416. Ultimately, the total international funding for the ten-year smallpox eradication effort came to $98 million, of which $34 million came from the WHO's regular budget. *Id.* at 459. Endemic countries spent approximately $200 million of their own fighting smallpox during the campaign. *Id.* at 1365. For comparison, the annual costs of smallpox itself, such as health care and lost wages for the victims, the price of vaccination programs, and the costs of adverse side effects, were estimated at $150 million per year for the United States, and $1.35 billion per year for the world as a whole in 1967. *Id.* The United States, the largest donor to the ISEP, was said to realize in savings the total of all its contributions to the program every twenty-six days. *Id.*

cated staff, under the inspired leadership of D.A. Henderson, on detail to the WHO from the U.S. Public Health Service;[108] generous donations of vaccine and other materials (the U.S.S.R. alone supplied 1.4 billion doses);[109] and remarkably timely innovations (both the relatively high-technology "jet injector" capable of vaccinating over one thousand people per hour,[110] and the much simpler bifurcated needle, suitable for manual use in the most primitive conditions).[111]

In addition, two organizational innovations, both still of current relevance, made prominent contributions to the WHO success. First, it was essential to improve the system for reporting disease outbreaks, diagnosing cases of interest, and recording accurate health statistics.[112] In 1967, it was estimated that only one to two percent of the actual smallpox cases were properly identified and tabulated by national public health officials.[113] A combination of incompetence, inadequate training, and fear of delivering bad news often led to drastic under-reporting and a failure to identify and treat emerging

108. The WHO professional staff assigned to smallpox eradication never numbered more than 150 and they coordinated activities in over fifty countries, involving 150 thousand workers. *Id.* at 423.

109. *Id.* at 469. The United States provided over 190 million doses, mostly to western and central African countries. *Id.* Eventually, endemic countries produced millions of vaccine doses for their own use. *Id.* at 468-69. It has been estimated that 2.4 billion doses of vaccine were administered as part of the ISEP. Radetsky, *supra* note 51, at 91.

110. FENNER ET AL., *supra* note 14, at 406. The jet injector was a device for forcing vaccine, under high pressure, through the skin. *Id.* It provided clean, safe, and highly reliable vaccination, and it proved very useful in situations where large groups of people could be assembled for vaccination. *Id.* at 577. However, in many locales, only smaller numbers were collected at any time, so the advantage was largely moot, and the machinery required significant training for proper operation, as well as bothersome maintenance encumbering its use in the field. *Id.* at 579.

111. *Id.* at 578. A bifurcated needle is one in which the tip is split into two prongs like a small fork. *Id.* at 569. The shape ensures delivery of an adequate amount of vaccine and minimizes waste. *Id.* The bifurcated needle was developed during the 1960s; it replaced a variety of conventional needles, lancets, and other devices that had proven less accurate and effective as delivery mechanisms. *Id.* at 568-69. The bifurcated needle could be easily sterilized for re-use; it was quite inexpensive ($5 per 1000); it was fully safe; it required no special handling or maintenance for use in the field; and unskilled workers, even the illiterate lay persons employed by the WHO campaign in many countries, could be adequately trained in its use within ten to fifteen minutes. *Id.* at 572-73. The bifurcated needle, therefore, quickly became the instrument of choice for the ISEP, displacing the jet injector and other applicators for most mass vaccination purposes. *Id.* at 579. The WHO eventually acquired some fifty million bifurcated needles and distributed them to almost all endemic countries. *Id.* at 572. Unlike most other vaccinations, smallpox protection is not provided by an injection through a hypodermic syringe. Instead, a droplet of vaccine is placed on the surface of the skin (usually the upper arm) and then driven through the skin by a cutting or puncturing motion. *Id.* at 568-69.

112. *Id.* at 173 (indicating that there was inaccurate diagnosis and reporting of cases in endemic countries); *see also* TUCKER, *supra* note 95, at 63.

113. FENNER ET AL., *supra* note 14, at 173.

epidemics in a timely fashion.[114] WHO officials undertook to educate local health officials, to develop streamlined monitoring equipment and systems, and to reward accuracy (including, in the latter stages of the ISEP, offering a cash bounty for anyone who could find a valid case of smallpox infection).[115]

Second, WHO experts eventually concluded that the original strategy of attempting to vaccinate *everyone* in a target country was both unattainable and unnecessary. So many remote villages could not be routinely monitored, so many nomads were impossible to track down, and so many babies were born each year that the herculean enterprise was doomed to frustration.[116] Instead, strategists eventually conceptualized and implemented a "surveillance-containment"[117] approach of promptly identifying and diagnosing any new smallpox outbreak and immediately dispatching a "quick reaction"[118] team to surround the area and vaccinate everyone inside the perimeter and everyone else who had possibly come into contact with the initial victims.[119] This approach, while still quite demanding of logistical sup-

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114. *Id.* at 516.

115. *Id.* at 447-48, 473-78, 1123. Eventually, the WHO offered a cash reward of $1000 to anyone who could locate an active case of smallpox. *Id.* at 1123. The heavily advertised program stimulated energetic searching for pox-like illnesses and facilitated the organization's efforts to investigate potentially-suspicious disease outbreaks, but the bounty was never collected. *Id.*

116. *Id.* at 482-83. The ISEP teams encountered enormous obstacles in reaching isolated communities and tribes around the world. *Id.* at 829 (indicating that ISEP confronted monsoons); *id.* at 1013 (rugged terrain); *id.* at 1018 (unmapped regions); *id.* at 1025 (native hostility to strangers); *id.* at 1233 (warfare in the Horn of Africa).

117. *Id.* at 482-85.

118. *Id.* at 493-94.

119. *Id.* Some in the WHO leadership and officials in many endemic countries were initially skeptical about the notion of de-emphasizing mass vaccination campaigns and ceding greater priority to the surveillance-containment approach (also known as "ring vaccination"—to treat everyone in a tight circle surrounding a discovered case). TUCKER, *supra* note 95, at 75-82. Eventually, however, the greater efficiency of the more selective approach was demonstrated, and the ISEP developed an enhanced capability to activate a "health radar system" to discover emergent smallpox cases in a timely manner and attack them with focused resources. *Id.* at 80-82. *See generally* FENNER ET AL., *supra* note 14, at 493-515 (discussing the strategy, implementation, and success of the ISEP's surveillance-containment approach for smallpox eradication).

Notably, 1973 was a watershed year in the development of the surveillance-containment strategy. Before then, relatively simple operations, combined with continuing mass vaccination efforts, had sufficed to eliminate smallpox from most previously endemic countries. *Id.* at 503. After September 1973, a more elaborate system of case detection was inaugurated, involving larger numbers of WHO and local health officials, to combat the disease in the handful of most persistent smallpox countries in South Asia and East Africa. *Id.*

Critical to the success of the operation was the fact that vaccination proved effective in warding off smallpox even if administered after the person had already been exposed to port and dependent upon valid, timely data, proved to be the answer, enabling the WHO to strike down variola in country after country.[120]

In the ISEP decade, teams of vaccinators eventually succeeded around the world, with smallpox transmission interrupted in much of Western Africa in 1968,[121] most of Asia becoming rid of the disease by 1972,[122] and only the Horn of Africa still showing active cases in 1975.[123] Finally, in 1977, the last naturally-occurring case of smallpox was recorded, in Ali Maow Maalin, a twenty-three-year-old cook in the coastal Somalian town of Merca.[124] After two more years of punctilious monitoring, the WHO proudly pronounced the world free of the disease, and no one in Somalia or elsewhere around the world has encountered endemic smallpox in the past quarter century.[125]

H. Laboratory Accidents

That triumph, however, was not quite the world's last experience with the disease. Startling laboratory accidents in England in 1973 and again in 1978 provide a suitably cautionary note for our public

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variola. *See id.* at 65. If the incipient victim could be identified and vaccinated within three or four days, protection was achieved. *See id.*

120. Mass vaccination campaigns also continued to be a foundation of the ISEP; if 80% of the population could be reached in that more routine way, the country would achieve a basic level of protection—referred to as "herd immunity"—that would enable the more focused surveillance-containment policy to succeed. FENNER ET AL., *supra* note 14, at 424, 484.

121. *Id.* at 849. The United States had previously undertaken a major smallpox interdiction effort in West Africa, demonstrating that a well-planned and moderately funded eradication program could succeed even in countries with entrenched poverty and underdeveloped health infrastructures. *Id.* at 908.

122. *Id.* at 528-29 (explaining that in 1972 smallpox in Asia remained endemic only in India, Pakistan, Bangladesh, and Nepal).

123. *Id.* at 534-35 (noting that in 1975, smallpox remained endemic only in Ethiopia, along with some re-importations of smallpox across the border into Somalia).

124. *Id.* at 1062. Although Mr. Maalin had previously volunteered as a WHO smallpox vaccinator, he had never been successfully vaccinated himself. *Id.* On October 12, 1977, he escorted some arriving smallpox patients on a short trip to an isolation camp and was exposed to the virus for only those few minutes. *Id.* at 1062-63.

125. World Health Assembly, Res. 33.3, 8th Plen. Mtg., May 8, 1980; FENNER ET AL., *supra* note 14, at 1104. The WHO procedures specified a two-year period of disease-free conditions before a country could be officially certified as being rid of endemic smallpox, and during that interval, vaccination campaigns and intense monitoring continued to investigate suspect cases and root out any rumors about additional smallpox outbreaks. FENNER ET AL., *supra*, at 1107-10.

WHO also instituted an International Commission for the Global Certification of Smallpox Eradication, to oversee the completion of the national monitoring programs. *Id.* at 1130. On December 9, 1979, this group issued its final report officially finding that the disease had been eliminated worldwide and promulgating nineteen recommendations for follow-up activities. *Id.* at 1134.

policy choices today.[126] In the earlier incident, an unvaccinated technician at the London School of Hygiene and Tropical Medicine observed a co-worker who was manipulating some variola samples on an open workbench. The observer subsequently fell ill, and was hospitalized with what was later diagnosed as a mild case of smallpox.[127] Before that diagnosis was registered, however, she was admitted to a general hospital ward, where she passed the infection to two visitors, who became the first smallpox fatalities in Britain in over a decade, and through them, to a nurse.[128]

The second, more bizarre, anomaly occurred in Birmingham five years later, nearly a year after the world's last "natural" case of smallpox had hit Somalia.[129] This time, the initial victim was a medical photographer, Janet Parker, working out of a small office and darkroom located one floor above the University of Birmingham's Department of Medical Microbiology.[130] Postmortem investigators concluded that variola might have crept silently upward through an unsafeguarded ventilation and service duct.[131] Diagnosis, once again, was not immediate and the photographer, who eventually became the last smallpox fatality on earth, soon passed the virus along to her mother, who survived.[132]

The 1978 Birmingham incident is particularly instructive regarding the failure of supposedly secure laboratory facilities. It had long been operated by Professor Henry S. Bedson, a leading authority on smallpox who had earned the implicit trust of United Kingdom and WHO health authorities, who consequently failed to inspect the shoddy reality lurking behind his purportedly state-of-the-art safety procedures.[133] When Bedson, quarantined at home for fear of his

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126. FENNER ET AL., *supra* note 14, at 1095-99; HOPKINS, *supra* note 43, at 98-99.

127. FENNER ET AL., *supra* note 14, at 1095-96; HOPKINS, *supra* note 43, at 98-99.

128. FENNER ET AL., *supra* note 14, at 1095-96; HOPKINS, *supra* note 43, at 98-99.

129. FENNER ET AL., *supra* note 14, at 1064-67; HOPKINS, *supra* note 43, at 99.

130. FENNER ET AL., *supra* note 14, at 1097-99; HOPKINS, *supra* note 43, at 99.

131. FENNER ET AL., *supra* note 14, at 1097-99; HOPKINS, *supra* note 43, at 99.

132. FENNER ET AL., *supra* note 14, at 1097-99; HOPKINS, *supra* note 43, at 99.

Twelve years prior to this incident, another medical photographer, who worked in the exact same suite of offices that Janet Parker was later to occupy, contracted smallpox (Variola minor) and accidentally triggered a significant outbreak of seventy-two cases of the disease in Birmingham, the West Midlands, and Wales. In that 1966 incident, investigators could not definitively conclude whether the virus had leaked upstairs from the laboratory, or whether the photographer had encountered the disease elsewhere. In Parker's case, however, there seemed to be no doubt about the origin of the infection. FENNER ET AL., *supra*, at 1098-1100; HOPKINS, *supra*, at 99.

133. Nigel Hawkes, *Science in Europe/Smallpox Death in Britain Challenges Presumption of Laboratory Safety*, 203 SCI. 855, 855-56 (1979); *see also* TUCKER, *supra* note 95, at 126-32 (describing the smallpox incident).

own exposure to the virus, realized the disastrous sequelae of his deceptive failure to adhere to the published protocols, he committed suicide.[134]

I. Post-Eradication Actions

In response to that disaster, and on the heels of the stunning ISEP success, WHO authorities adopted a series of organizational and institutional measures that still shape the smallpox debate two decades later.[135] First, they resolved to reduce the number of locations at which variola samples and residues were held.[136] For most of human history, of course, infectious smallpox materials were everywhere and all countries had ready access.[137] During and after the ISEP, however, only a relatively small number of facilities retained such items. By 1977, only eighteen laboratories reported that they had any relevant variola samples in their freezers.[138] Upon prodding by the WHO, that number was gradually reduced to seven in 1979 and to only two in 1983.[139]

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134. Radetsky, *supra* note 51, at 92; *Smallpox: Ignorance Is Never Bliss*, 277 NATURE 75, 77 (1979). Bedson had agreed with prior WHO inspection teams that his laboratory facilities and procedures were not up to modern safety standards and should not host further variola work. However, he misled both WHO and British authorities about his intentions and greatly accelerated the pace of the research in order to complete it before the facility was to be closed at the end of the year. In a suicide note, he wrote, "I am sorry to have misplaced the trust which so many of my friends and colleagues have placed in me and my work." Radetsky, *supra* note 51, at 92.

135. TUCKER, *supra* note 95, at 132-33. For the most part, the WHO does not have the power to issue legally-binding instructions to its member countries. With few exceptions, it is limited—even on top priority matters of global health and communicable diseases, such as smallpox eradication and the management of the variola virus residuals—to making recommendations, leading by example, providing scientific expertise and support, and applying moral or political suasion. FENNER ET AL., *supra* note 14, at 444.

136. FENNER ET AL., *supra* note 14, at 1338-39. In 1976, the World Health Assembly requested all governments and laboratories to cooperate in compiling an international registry of facilities retaining stocks of variola virus, and urged those institutions which did not require such inventories to destroy them. World Health Assembly, Res. 29.54, 12th Plen. Mtg., May 19, 1976.

137. FENNER ET AL., *supra* note 14, at 1339-40. No one knew how many laboratories might hold variola stocks, but a 1975 survey revealed that at least seventy-five facilities, dispersed all over the world, had some sort of smallpox inventories. *Id.* at 1338-39.

138. *Id.* at 1340.

139. *Id.* at 1340-41. The 1979 Global Commission, and subsequently the World Health Assembly, recommended that no more than four WHO "collaborating centers" should be designated to hold and to handle variola stocks, and all other facilities should destroy their inventories or transfer them to an approved collaborating center. World Health Assembly, Res. 33.4, May 1980. By 1983, only two facilities held known variola stocks: the Centers for Disease Control in Atlanta and the Ivanovsky Institute for Viral Preparations in Moscow. FENNER ET AL., *supra* note 14, at 1341; TUCKER, *supra* note 95, at 134-36.

The physical security of those last two installations, now designated as WHO Collaborating Centers for smallpox research, has naturally become a matter of international concern. The CDC in Atlanta, Georgia, has not encountered untoward incidents; it reportedly stores its 450 variola samples in the innermost, rigidly guarded portions of the installation with secret and redundant layers of protection.[140] But at the same time, it is notable that other leading United States institutions (including those with the strongest reputations and safety standards) that formerly conducted variola work have hardly been free of accidents or safety and security lapses in handling other extremely hazardous pathogens.[141]

The Soviet variola stash was initially deployed at the Ivanovsky Institute for Viral Preparations in Moscow, but shockingly inadequate protections there alarmed the authorities.[142] In 1994, those 120 samples were suddenly and without advance notice to, or permission from, the WHO transferred to the Vector facility in Koltsovo, near

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140. Charles Siebert, *Smallpox Is Dead: Long Live Smallpox*, N.Y. TIMES MAG., Aug. 21, 1994, at 30, 34. Some feel we need to tighten security at the CDC even further in the aftermath of September 11. Ceci Connolly, *Smallpox Vaccine Plan Called Lacking*, WASH. POST, Nov. 30, 2001, at A39.

141. Arjun Srinivasan et al., *Glanders in a Military Research Microbiologist*, 345 NEW ENG. J. MED. 256, 256 (2001) (describing accidental infection of a U.S. microbiologist by glanders, a possible biological weapons agent, at a U.S. Army laboratory); *Anthrax Contaminates Army Lab; Employee Tests Positive*, N.Y. TIMES, Apr. 20, 2002, at A11 (describing an anthrax leak into a hallway and administrative area at Fort Detrick, the U.S. Army's leading biological research institute); Rick Weiss & David Snyder, *Anthrax Leaks a 2nd Time at Army Lab*, WASH. POST, Apr. 24, 2002, at B01 (describing a second anthrax leak at Fort Detrick in which one worker tested positive for anthrax exposure); *see also Bioweapons Labs 'Could Unleash Forgotten Diseases,'* 412 NATURE 470 (2001); *Report Finds Easy Lab Access to Deadly Pathogens*, REUTERS, May 7, 2002 (finding that many of the U.S. Department of Agriculture's 124 laboratories, including those housing deadly biological agents, were vulnerable to theft, dangerously open to casual visits by unauthorized strangers, and unable to maintain valid records about their pathogen holdings), *at* http://preventdisease.com/news/articles/easy_lab_access_pathogens.shtml (last visited May 21, 2003).

142. *See* Howard Witt, *Russian Lab Sits on Dread Secret: Smallpox Cache; Fears of Terrorists' Stealing Virus*, ARIZ. REPUBLIC, Feb. 10, 1994, at A15 (noting that the variola stocks at the Ivanovsky Institute were woefully unprotected). The laboratory's deputy director was quoted as acknowledging, "If some terrorist really wants to do something with this smallpox virus, there is nothing that can stop him." *Id.* The WHO had not inspected the facility in the previous eight years. *Id.* Another commentator describes the facilities at the Institute in 1982 as "deteriorating, its supplies of water and electricity were unreliable, and the security arrangements limited to an iron fence topped with barbed wire and a small brick guardhouse near the front gate." TUCKER, *supra* note 95, at 174; *see also* Carl Levitin & Alison Abbott, *Electricity Debt Could Mean Lights Out for Russian Virus Institute*, 407 NATURE 5, 5 (2000) (reporting that the Ivanovksy Institute, unable to pay the bills of its electricity supplier, may suffer a power outage that would lead to the loss of rare viral holdings).

Novosibirsk in southern Siberia.[143] Physical custody there seems far more certain, but other, equally ominous portends may be lurking, as surveyed below.[144]

Those two inventories, of course, cannot confidently be advertised as being the "last" or the "only" variola stocks left in the world. They are, instead, merely the final deposits that the general public knows about. Persistent rumors, impossible to verify or to dismiss, suggest that additional stashes may have been secreted away by rogue laboratories, military zealots, or unrepentant countries, without official acknowledgment or authorization from the WHO.[145] The location of any such caches and the identity and motivations of their possessors remain obscure, but senior United States government officials and private observers alike concede the possibility that Russia, North Korea, Iraq, or others have not declared or destroyed all the smallpox materials they once possessed.[146]

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143. A WHO inspecting team of biosafety and orthopoxvirus experts reviewed the safety aspects of the Vector facility in June 1995, and the facility was formally designated as a collaborating center in 1997. World Health Organization, Communicable Disease Prevention and Control: Smallpox Eradication—Destruction of Variola Virus Stocks, EB97/14, Sept. 13, 1995; *see also* Vladimir Pokrovskiy, *Vector Science Center's Achievements, Financial Need Described*, MOSCOW OBSHCHAYA GAZETA, May 8-14, 1997 (discussing Vector's safety standards as including "a six-story reinforced concrete cube" which houses the virus) (translated from Russian).

144. As discussed below, Vector was for many years the leading component of the Soviet Union's biological weapons program. Some feared that the Moscow variola samples were transferred to Koltsovo largely to provide "cover" for weapons-related smallpox work that would continue there, now under the guise of a civilian, WHO-approved institute. Richard Preston, *The Demon in the Freezer*, NEW YORKER, July 12, 1999, at 44, 46.

145. Other, more innocent, residual variola caches might be available, too. For example, there may still be unlabeled ampoules of the virus buried in the inner recesses of any laboratory's deep-freeze cabinet, some of which are poorly inventoried and rarely purged. TUCKER, *supra* note 95, at 136-37 (stating that "[m]ost virologists were poor librarians . . . , and they rarely catalogued or cleaned out their laboratory freezers on a regular basis. Thus, over the years, specimens of variola virus tended to get lost among the mass of ice-encrusted tubes and bottles."). Given the inadequacies of human memories, and the normal turnover in personnel, it is possible that long-forgotten samples might surface at any time. Indeed, previously-undeclared variola virus stocks were discovered in two locations in 1979: a laboratory in California and one in Tanzania. *Id.* at 137; *see also* FENNER ET AL., *supra* note 14, at 1341. Moreover, some have posited that viable variola samples may be extracted from prehistoric smallpox victims among northern cave dwellers who contracted the disease, died from it, and were frozen in near-cryogenic conditions in the permafrost, which might have preserved the virus for discovery centuries later. TUCKER, *supra*, at 161-62; Pokrovskiy, *supra* note 143 (stating the opinions of researchers from Vector regarding the threat of smallpox re-emerging from the Siberian permafrost zone).

146. David Brown, *Destruction of Smallpox Samples is Reassessed*, WASH. POST, Mar. 15, 1999, at A01 (quoting experts who suspect hidden variola virus samples exist outside the WHO repositories); Steve Goldstein, *Smallpox a Big Terrorism Worry*, SEATTLE TIMES, Apr. 25, 2000, at A8 (quoting a senior scientist at Sandia National Laboratories as saying "it's far more likely than not" that variola virus is held outside the known repositories); *Smallpox: U.S. to*

In addition to attempting to consolidate and conserve the variola stocks, the WHO undertook in 1980 to procure and maintain indefinitely a suitable stockpile of viable, freeze-dried vaccine as a precaution against any future resurgence of the virus.[147] As initially envisioned, the organization itself would permanently retain at least 200 million doses and suitable bifurcated needles in two widely-dispersed locations.[148] Individual countries were expected to conserve another 100 million high-quality vaccine doses in their respective national inventories.[149] Relatively quickly, however, that collective resolve faded: difficulties in sustaining quality and temperature controls led to the WHO stocks being reduced and consolidated in Switzerland;[150] the production of any new vaccine was abruptly halted in most nations;[151] and the ability to quickly generate additional supplies atrophied.[152] The current WHO inventory of smallpox vaccine totals no more than 500,000 doses, and the various national supplies—of starkly uneven quality—may have accumulated to only 60-110 million by 2000.[153]

In connection with the elimination of the immediate threat of smallpox, the WHO also recommended the termination of all coun-

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Oppose Destruction of Last Samples, AM. HEALTH LINE, April 23, 1999 (quoting Ken Bernard of the National Security Council staff as stating, "We are relatively sure that most of the virus is in the two declared stocks. There's just no way to ensure that if we destroy the two declared stocks that we will destroy every smallpox virus that exists.").

147. *See* FENNER ET AL., *supra* note 14, at 1267-70 (detailing WHO plans to maintain suitable stores of smallpox vaccine).

148. *See id.* at 1267-68 (stating that by 1985, the organization actually held about 300 million vaccine doses and 3.7 million bifurcated needles in repositories in Geneva and New Delhi).

149. *See id.* at 1270 (stating that in 1985, twenty-two countries reported holding national reserves of smallpox vaccine, totaling over 100 million doses, but only about 84 million doses were being properly maintained).

150. *Id.* at 1268 (stating that after persistent fluctuations in refrigeration and a serious flood, the New Delhi vaccine inventory was transferred to Switzerland in 1984).

151. *Id.* at 1270 (stating that in 1975, eighty-four laboratories in seventy-six countries produced smallpox vaccines, but by 1985 only fourteen laboratories in eleven countries were producing minimal amounts of new vaccine).

152. *Id.*

153. WORLD HEALTH ORG., *supra* note 52, at http://www.who.int/emc/diseases/smallpox/factsheet.html. In 1985, the relevant WHO committee determined that it was no longer necessary for the WHO to maintain its vaccine inventory, and the organization's holdings quickly plummeted. FENNER ET AL., *supra* note 14, at 1269-70; Henderson et al., *supra* note 43, at 2131-32 (stating that "[a]lthough quantities of vaccine have also been retained by a number of other countries, none have reserves large enough to meet more than their own potential emergency needs. WHO has 500,000 doses."). Similarly, national vaccine stocks declined, both in quantity and quality. James W. LeDuc & John Becher, *Current Status of Smallpox Vaccine*, 5 EMERGING INFECTIOUS DISEASES 593, 593 (1999).

tries' routine vaccination programs.[154] Because of the danger of side effects, including a statistically foreseeable number of infant and childhood deaths, public health authorities in many nations had quickly suspended automatic vaccination of the civilian populations whenever their countries became reliably smallpox-free.[155] In the United States, for example, routine smallpox vaccination became a thing of the past in 1972, except for some military personnel and health researchers deemed to be at special risk.[156] Most of the rest of the world followed suit in the 1970s or early 1980s.[157]

Finally, in the afterglow of smallpox eradication, WHO expert committees also inaugurated a spirited debate about whether to destroy those last known remaining samples of the variola virus housed in the United States and Russia.[158] In 1985, a leading WHO committee surveyed sixty recognized academic and public health experts in twenty-one countries, finding that only five held the view that variola should be retained indefinitely for research purposes.[159] Accordingly, in 1986 and again in 1990, the relevant WHO expert groups unani-

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154. FENNER ET AL., *supra* note 14, at 1264-67.

155. *Id.* at 1264-65 (stating that while fifty-two WHO member countries were still conducting routine vaccination programs in 1980, routine vaccination ceased in all countries by 1984).

156. *See* Henderson et al., *supra* note 43, at 2131-32 (noting that routine vaccination in the U.S. ceased in 1972); U.S. CTRS. FOR DISEASE CONTROL, SMALLPOX QUESTIONS AND ANSWERS: THE DISEASE AND THE VACCINE (2003), at 7, *available at* http://www.bt.cdc.gov/agent/smallpox/overview/pdf/faq (last updated Mar. 31, 2003). Between the last smallpox case in the United States in 1949 and the termination of routine vaccination in 1972, the country tolerated the incidence of adverse side effects from vaccination in order to preserve the bulwark against imported smallpox. FENNER ET AL., *supra* note 14, at 309-10. In 1963, for example, fourteen million vaccinations were conducted, resulting in 132 cases of severe complications and 7 deaths. *Id.* at 309. At that rate, between 1949 and 1972, there may have been 3000 cases of severe vaccinial complications and 150 deaths. *Id.*

Analysts then compared two hypothetical situations: a continuation of routine smallpox vaccination in the United States from 1970 to 2000, and suspension of vaccination except for high-risk groups (hospital workers, international travelers, and military inductees), coupled with a surveillance-containment program to deal immediately with any imported cases. *Id.* (citing a 1969 study by J.M. Lane and J.D. Millar). The first scenario would have resulted in 210 vaccination induced deaths. *Id.* The second scenario would cause an equivalent number of deaths only if there were as many as twenty-one separate importations of smallpox during the period. *Id.*

157. FENNER ET AL., *supra* note 14, at 1264-66 (discussing the cessation of routine vaccination programs in various countries).

158. *See* D.A. HENDERSON, DELIBERATIONS REGARDING THE DESTRUCTION OF SMALLPOX VIRUS: A HISTORICAL REVIEW, 1980-1998 (Ctr. for Civilian Biodefense Strategies, Comm. of the Inst. of Med., Working Paper 1998) (providing conflicting points of view), *at* http://www.hopkins-biodefense.org/pages/news/deliberations.html (last visited Apr. 2, 2003); TUCKER, *supra* note 95, at 169-74 (outlining the respective positions of those who favored destruction of the remaining virus and those who supported retention).

159. *Scientific Activities*, 64 BULL. WORLD HEALTH ORG. 801, 801-02 (1986).

mously recommended destruction of the two repositories, eventually setting a target date of December 31, 1993.[160] When that deadline slipped by, the objective was re-cast as June 30, 1995.[161]

Other supposedly final deadlines for variola's destruction have similarly come and gone without dispositive action,[162] despite what still appears to be overwhelming global sentiment in favor of eradication.[163] A 1998 survey, for example, found seventy-four WHO member countries expressing themselves in favor of prompt incineration, four undecided, and one opposed—but the four undecided nations were Britain, France, Italy, and the United States, and the sole opponent was Russia.[164] In May 1999, the WHO, at America's urging, again punted the issue into the future, deciding "to authorize temporary retention up to not later than 2002"[165] for the purpose of permitting additional international research on antiviral agents, improved vaccines, genetic mapping, and augmented diagnostic and detection capabilities.[166] But in 2002, even that deadline was erased, when the

160. *See id.* (stating that the 1986 Committee also recommended that global reserves of vaccine were no longer necessary, seed stocks should continue to be maintained, and smallpox vaccination of military personnel should be terminated); *see also* HENDERSON, *supra* note 158, *at* http://www.hopkins-biodefense.org/pages/news/deliberations.html; *Destruction of Variola Virus: Memorandum from a WHO Meeting*, 72 BULL. WORLD HEALTH ORG. 841, 843 (1994).

161. By this time, considerable controversy had arisen about the destruction decision, and the issue was debated by virologists and others inside and outside the WHO structure. When the relevant WHO committee assembled in 1994, cracks in the previous consensus emerged. While the members were once again unanimous that the two variola repositories should be eliminated, there was disagreement about precisely when that step should be taken. Eight members favored June 30, 1995, while two others would have postponed the action for five more years to permit additional scientific research. *Destruction of Variola Virus*, *supra* note 160, at 842-43; *see also* TUCKER, *supra* note 95, at 177 (discussing the meeting of the Ad Hoc Committee on Orthopoxvirus Infections and its ultimate decision to recommend destroying remaining stocks on June 30, 1995).

162. *See* TUCKER, *supra* note 95, at 187-89, 213-17.

163. *See* Smallpox Eradication: Destruction of Variola Virus Stocks: Report by the Secretariat, World Health Org. Exec. Bd. 109th sess., Provisional Agenda Item 3.14, at 3-4, EB 109/17 (2001) (noting the sixteen member Advisory Committee on Variola Virus Research's conclusion that variola research should continue).

164. TUCKER, *supra* note 95, at 190; Meredith Wadman, *Scientists Split on US Smallpox Decision*, 398 NATURE 741, 741 (1999).

165. World Health Assembly, Res. 52.10, 9th Plen. Mtg., Agenda Item 13, at 1, A52/VR/9 (1999), *available at* http://www.who.int/emc/pdfs/cwha5210.pdf (last visited Mar. 10, 2003); *see also* Smallpox Eradication: Destruction of Variola Virus Stocks, Report by the Secretariat, World Health Org. 54th World Health Assembly, Provisional Agenda Item 13.7, at 1, A54/16 (2001) (noting the deadline extension).

166. World Health Assembly Res. 52.10, *supra* note 165, at 1. Under the resolution, any such research is to be funded by member states and "conducted in an open and transparent manner only with the agreement and under the control of WHO." *Id.* The Director-General has appointed a new group of experts to advise the WHO on the progress of the research and on inspection of the facilities where variola activities are conducted. WHO,

WHO again bowed to American pressure and deferred the destruction of the variola stocks once more—this time without even setting a new due date for the virus's ultimate incineration.[167]

The international debate on variola destruction quickly outgrew the channels of the scientific literature, and it has continuously intensified.[168] Proponents of prompt incineration argue that only by destroying the virus can we be assured that it will never escape its current confinement and again ravage humankind; that we no longer require access to live, intact variola for scientific research purposes; and that destruction provides a necessary symbolic coda to the eradication of the disease, a human triumph that remains incomplete as long as any residue of the virus lingers.[169] Retentionists, on the other hand, argue that there is possible future value in additional scientific research on variola;[170] that it is unwise to destroy the two stockpiles we know about, so long as there may remain other secret stashes possibly accessible by hostile or rogue regimes; and that it is ethically problematic for human beings to deliberately destroy another life form.[171]

Report by the Secretariat, Smallpox Eradication: Destruction of Variola Virus Stocks, at 1, EB 106/3 (2003).

167. World Health Assembly, Res. 55.15, 9th Plen. Mtg., Agenda Item 13.16, at 1, A55/VR9 (2002). Some countries, notably China, had advocated setting a new fixed date for destruction of the samples, but that proposal was dropped. The director of the Vector laboratory where the Russian samples are stored has interpreted the WHO action as forecasting "another 5 to 7 years" of continued retention and research on the samples. Richard Stone, *World Health Body Fires Starting Gun*, 296 SCI. 1383, 1383 (2002).

168. The public forum for debate was triggered by a pro/con debate in *Science* magazine in 1993. *See* Wolfgang K. Joklik et al., *Why the Smallpox Virus Stocks Should Not Be Destroyed*, 262 SCI. 1225 (1993); Brian W.J. Mahy et al., *The Remaining Stocks of Smallpox Should Be Destroyed*, 262 SCI. 1223 (Nov. 19, 1993). As recent events have stimulated the public's interest in bioterrorism and related topics, smallpox has become a prominent subject for popular culture, including novels, television programs, and video games. Ruth J. Katz, Editorial, *How to Prepare for Smallpox*, WASH. POST, June 1, 2002, at A19 (television); Margaret Talbot, *Losing the Home Front*, N.Y. TIMES, Dec. 22, 2002, § 6, at 13 (video games).

169. Mahy et al., *supra* note 168, at 1224. As Russian smallpox scientist Otar Andzhaparidze put it, if the planet's epochal struggle against variola were to end without total eradication, "it would be as if a piece of music were to end before the final note was struck." Siebert, *supra* note 140, at 32.

170. Joklik et al., *supra* note 168, at 1225-26 (suggesting that further inquiries may enhance our ability to deal with smallpox should it ever recur, with other viral diseases that may operate along similar cellular pathways, and with human immunology more generally). *See generally* COMM. ON THE ASSESSMENT OF FUTURE SCIENTIFIC NEEDS FOR LIVE VARIOLA VIRUS, BD. OF GLOBAL HEALTH, INST. OF MED., ASSESSMENT OF FUTURE SCIENTIFIC NEEDS FOR LIVE VARIOLA VIRUS (1999) [hereinafter INST. OF MED.] (analyzing the scientific advances, including development of improved vaccines, antiviral medications, and diagnostic and detection equipment—possibly useful against a range of other viruses, in addition to variola—that might be achievable through additional research on smallpox).

171. TUCKER, *supra* note 95, at 172-73. Some leading scientists, noting that a virus does not meet the traditional biological criteria defining "life," conclude that any philosophical

J. If Smallpox Escaped Today

The most horrifying scenarios—and the images that animate much of the debate about the future of the virus samples—spring from the irreducible possibility that as long as variola exists anywhere on earth, we cannot be one hundred percent confident that it could never return to the human population.[172] Several such pathways may be imagined because no laboratory, even one as diligent and attentive to security as the CDC, can ever be absolutely protected. The recent experience with high-level spies at the FBI and CIA, for example, reminds us that disloyal or disgruntled employees may be found in any institution as long as greed, ideology, and blackmail remain human motivations.[173] Natural disasters, too, can pose threats, as earthquakes and hurricanes can strike with little warning, unleashing nature's fury against even reinforced buildings. Likewise, the skill and discipline of the September 11, 2001 terrorists underscore the fact that no facility can be immunized from the threat of hijacked airliners turned into flying bombs. Reportedly, the CDC itself was considered a possible target of an additional diverted aircraft on that horrific day.[174]

If variola did somehow escape its current frozen storage and invade the biosphere today, the consequences could be monumental. In 2003, an overwhelming number of the human population is precariously vulnerable. First, there are relatively few survivors of earlier smallpox attacks who possess lifetime immunity. Second, most countries stopped routine vaccination two or three decades ago; therefore upwards of half the world's population, born after that period, has never been vaccinated, and the protection accorded to older people by their childhood vaccinations has now largely worn off.[175]

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or ethical squeamishness about eradicating the last variola samples is misplaced; however, others would admit a broader range of moral considerations as relevant to the issue. FENNER ET AL., *supra* note 14, at 1339 (arguing that the only consideration should be whether maintaining the virus is necessary for scientific research).

172. *See* Siebert, *supra* note 140, at 55 (noting some scenarios that might result in the virus's re-introduction into the human population).

173. *See* Walter Pincus, *Catch a Spy—And Look What Happens*, WASH. POST, Mar. 25, 2001, at B01 (noting several recent, high-profile cases in which American government officials were exposed as spies for the Soviet Union or other countries).

174. Sheryl Gay Stolberg & Judith Miller, *Bioterror Role an Uneasy Fit for the C.D.C.*, N.Y. TIMES, Nov. 11, 2001, at 1A (noting that the Federal Bureau of Investigation passed along a tip that another hijacked aircraft appeared headed toward Atlanta, and possibly toward the CDC, which then promptly evacuated its premises).

175. William J. Bicknell, *The Case for Voluntary Smallpox Vaccination*, 346 NEW ENG. J. MED. 1323, 1323 (2002) (stating that the 119 million Americans born after the termination of mass vaccinations would be fully vulnerable to smallpox); D.A. HENDERSON, RISK OF A DELIBERATE RELEASE OF SMALLPOX VIRUS; ITS IMPACT ON VIRUS DESTRUCTION (Ctr. for Civilian Biodefense Stud. Working Paper 1999 (stating that "in most communities, at least 90% of

In all earlier periods of human history, smallpox epidemics, as horrible as they were, knew some natural limits. When the virus ravaged a particular community, mostly striking children who had been born since the last major outbreak, it would eventually run out of fresh victims because most of the older local people were protected via their exposure to, and survival of, prior smallpox waves. Today, however, our "herd immunity"[176] has been lost—the nervous bulk of the American and global population is fully exposed.[177]

Moreover, there is no certainty that a case of smallpox today would be quickly diagnosed and treated as such. No one has had the occasion to make that particular identification for over two decades, so the routines for prompt assessment and treatment have not been practiced.[178] Our capacity for isolation and quarantine have likewise atrophied, and many states' public health laws and institutions have fallen into desuetude.[179]

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the population will be fully susceptible to smallpox with perhaps 20% of adults having some protective immunity and none of the children"), *at* http://www.hopkins-biodefense.org/pages/agents/risk.html (last visited Apr. 2, 2003); WORLD HEALTH ORG., *supra* note 52, *at* http://www.who.int/emc/diseases/smallpox/factsheet/htm. Few people received more than one smallpox vaccination, but even a relatively old vaccination might accord some degree of protection against a subsequent smallpox infection, perhaps lessening the severity of the disease or its communicability. Henderson et al., *supra* note 43, at 2131.

176. *See* P. Fine, *Herd Immunity: History, Theory, Practice*, 15 EPIDEMIOLOGIC REV. 265-302 (1993) (defining herd immunity as "the resistance of a group of people to attack by a disease to which a large proportion of the members are immune, thus lessening the likelihood of a patient with a disease coming into contact with a susceptible individual"); *Smallpox: Increasing Herd Immunity Would Enhance Post-Bioterrorist Attack Intervention*, VIRUS WKLY., Jan. 14, 2003, at 16 (noting that a program of "pre-emptive voluntary vaccination and vaccination of first responders . . . could enhance the effectiveness of post attack intervention").

177. In this respect, the global situation regarding vulnerability to variola is more akin to that of the native peoples of the New World when they first encountered smallpox imported from Europe in the sixteenth and seventeenth centuries. Because none of them had acquired immunity by surviving earlier epidemics, entire populations were simultaneously impacted, and death rates far exceeded those common in locations where smallpox episodes were a recurrent feature of communal experience. *See* FENNER ET AL., *supra* note 14, at 238-40 (chronicling the impact of smallpox upon early settlers to North America); TUCKER, *supra* note 95, at 9-10 (describing Spanish conquistador Hernando Cortes marching his troops into the Aztec capital on August 13, 1520 to find the streets lined with the bodies of smallpox victims). Of course, the availability today of an efficacious vaccine radically alters the comparison.

178. *See* Sydney J. Freedberg Jr. & Marilyn Werber Serafini, *Be Afraid, Be Moderately Afraid*, 31 NAT'L J. 806, 813 (1999) (noting that when a patient presents flu-like symptoms, doctors will not immediately turn their attention to the possibility of biological weapons); Lawrence K. Altman, *Smallpox Vaccine Knowledge Found Lacking*, N.Y. TIMES, May 10, 2002, at A32 (reporting that public health professionals and the general public are ill-informed about the dangers of smallpox and vaccination).

179. *See Bioterrorism Preparedness: CDC's Public Health Response to the Threat of Smallpox*, Testimony Before Sen. Comm. on Appropriations, Subcomm. on Labor, HHS, Educ., and Related Agencies, 107th Cong., at 3 (2001) (stating that the "CDC is creating diagnostic

In sum, the world's heroic triumph over smallpox—perhaps the single greatest public health accomplishment in history—remains incomplete. Even in 1973, when the prospect of success in the ISEP was at last coming within reach, the seeds of the current dilemma could be discerned: should we retain the last residues of variola as a sort of planetary insurance policy against contingent future needs and as the substrate for additional research activities, or should we promptly destroy it to further minimize the probability of future disastrous outbreaks?

II. MILITARY AND TERRORIST THREAT OF SMALLPOX AS A BIOLOGICAL WEAPON

A. *Biological Weapons in Combat*

The world's experience with disease as an implement of warfare is long, diverse, and unspeakably nasty. Certainly, military officials have always had to take into consideration the *accidental* outbreaks of deadly or incapacitating illnesses—smallpox prominent among them—that could decimate the troops or rob them of their fighting fitness at unpredictable moments.[180] Fragmentary historical records suggest that it may have been smallpox that killed one-quarter of Athens' soldiers and innumerable civilians in 430 B.C., undermining the city-state in its interminable warfare with Sparta;[181] that Alexander the Great's footsoldiers may have suffered brutally from smallpox in 327 B.C. while invading India;[182] and that the Great Wall of China could

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and epidemiological performance standards for state and local health departments and will help states conduct drills and exercises to assess local readiness for bioterrorism"), *available at* http://ohrp.osophs.dhhs.gov/dpanel/cdtest.pdf (last visited Feb. 1, 2003); George J. Annas, *Bioterrorism, Public Health, and Civil Liberties*, 346 NEW ENG. J. MED. 1337, 1337-38 (2002) (noting that "the CDC has advised all states to review the adequacy of their laws, with special attention to provisions for quarantining people in the event of a smallpox attack"); Matthew K. Wynia & Lawrence Gostin, *The Bioterrorist Threat and Access to Health Care*, 296 SCI. 1613, 1613 (2002) (discussing crucial obstacles to U.S. public health preparedness); Laura Meckler, *Smallpox Defense Includes Quick Use of a Quarantine*, DETROIT FREE PRESS, July 9, 2002 (reporting that federal health officials are preparing contingency plans for mandatory quarantine of Americans who might be exposed to a smallpox patient), *at* http://www.freep.com/news/health/pox9_20020709.htm (last visited Apr. 2, 2003).

180. Incapacitating an enemy soldier might sometimes be even more advantageous than killing him, because a sick or injured belligerent would consume far more of his colleagues' time, energy, and resources than would a dead one. PAUL E. STEINER, DISEASE IN THE CIVIL WAR: NATURAL BIOLOGICAL WARFARE IN 1861-1865, at 35-36 (1968).

181. FENNER ET AL., *supra* note 14, at 214-15; HOPKINS, *supra* note 43, at 19.

182. FENNER ET AL., *supra* note 14, at 214; HOPKINS, *supra* note 43, at 17.

repulse the invading Huns, but not the virus they injected into the empire in 243 B.C.[183]

Centuries later, smallpox accompanied, and materially assisted, the Spanish conquistadors in overwhelming the indigenous peoples of Central and South America.[184] Because the Aztecs, Mayans, and Incas had never previously encountered variola, they were all fully susceptible to it, whereas the Spanish, who had survived their individual bouts with smallpox, seemed invulnerable.[185] Millions of Native Americans died precipitously from variola, and their civilizations fell in sequence to the vastly outnumbered invading forces of Hernando Cortez and Francisco Pizarro.[186] Likewise, the various participants in the European colonization of North America,[187] the French and Indian War,[188] the American Revolution,[189] and the U.S. Civil War were buffeted by a variety of uncontrollable diseases, including smallpox, that slashed their military effectiveness.[190]

Further, *deliberate* applications of what we would now term biological weapons (BW) and chemical weapons (CW), collectively known as CBW, had been routinely undertaken throughout history.[191] For example, ancient warriors episodically attempted to foul each others'

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183. FENNER ET AL., *supra* note 14, at 216; HOPKINS, *supra* note 43, at 18, 165-67.

184. FENNER ET AL., *supra* note 14, at 236-38; HOPKINS, *supra* note 43, at 205-15.

185. FENNER ET AL., *supra* note 14, at 236-37; HOPKINS, *supra* note 43, at 207.

186. FENNER ET AL., *supra* note 14, at 236-38; HOPKINS, *supra* note 43, at 205-15.

187. HOPKINS, *supra* note 43, at 234-45 (noting that smallpox brutalized Indian villages and European settlements alike during the early North American colonial period).

188. *Id.* at 245 (noting that smallpox affected battles during the French and Indian War).

189. *Id.* at 257-62 (asserting that British troops were generally more frequently variolated than were colonials, inspiring fears that they might initiate the deliberate spread of smallpox as a battlefield tactic).

190. *Id.* at 274-77 (noting that during the Civil War, smallpox affected the South more because the Confederacy had less access to reliable vaccination).

191. *See* Flowerree, *supra* note 24, at 999; TUCKER, *supra* note 95, at 19-21. The three partially-overlapping categories of ordnance must be distinguished. Essentially, a "biological weapon" (such as smallpox or anthrax) relies upon a living organism (or upon infective material derived from such an agent) that causes a disease by reproducing itself inside humans, animals, or plants. Flowerree, *supra*, at 999. A "chemical weapon" (such as mustard gas or nerve gas), in partial contrast, relies upon a substance—in solid, liquid, or gaseous form—that causes direct toxic effects (deadly or incapacitating, long or short term) to the tissues, organs, or functions of its subjects. *Id.* A "toxin weapon" (such as rattlesnake poison or tricothecene) is a sort of grey area. It embraces chemical substances that are produced naturally by living organisms (and the various synthetically produced analogues of those natural substances) that can directly harm a target, without reproducing themselves inside it or creating a "disease." *Id.* Although these definitions are imprecise, and although scientific reality sometimes confounds our ability to categorize novel weapons concepts into discrete pigeonholes, the existing structures are the best available. William Lawler, *Progress Towards International Control of Chemical and Biological Weapons*, 13 U. TOL. L. REV. 1220, 1222-26 (1982) (discussing how the distinctions between biological

wells and rivers with diseased animals or other toxins.[192] In one notorious incident, fourteenth century Tartars besieging the Crimean city of Caffa catapulted plague-infested cadavers over the city walls, triggering a debilitating epidemic, which fleeing merchants then transported throughout the known world.[193]

Most infamously, during the latter stages of the French and Indian War, the British North American commander, Sir Jeffrey Amherst, plotted with his subordinates to dispense smallpox-infested blankets among the Indians threatening Fort Pitt in western Pennsylvania, exhorting his troops to: "Try Every other Method that can Serve to Extirpate this Execrable Race."[194] Shortly thereafter, a devastating smallpox epidemic indeed broke out among the Mingoes, Delawares, and Shawanoes of the Ohio River valley, although it is not completely clear from the historical record whether the British treachery was responsible.[195] Similarly, an eighteenth century white trader, furious that Indian raiders had stolen some of his equipment, exacted his revenge by presenting them, ostensibly as a token of peace, with a keg of rum wrapped in a flag that had been contaminated with variola—an early model of incipient biological terrorism.[196]

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and chemical weapons played a role in strained early efforts toward disarmament in the United Nations).

192. Ancient Indian, Greek, and Roman literature each abound with references to poisons being wielded in combat against an individual, an army, or a city. The true military effectiveness of these primitive potions and projectiles is hard to assess, but the concept of using biology and chemistry in combat—as well as the pattern of the public being revolted by that use—were well-established even before New Testament times. John Ellis van Courtland Moon, *Controlling Chemical and Biological Weapons Through World War II*, *in* II ENCYCLOPEDIA OF ARMS CONTROL, *supra* note 24, at 657 (stating that prohibitions against poisoning weapons, wells, and food were honored in India, by "the *Artharva Veda* (ca. 1500-500 B.C.) and the *Law of Manu* (ca. 200 B.C.-A.D. 200)," and "classical Greeks and Romans saw [such methods of poisoning] as a violation of *ius gentium*, the law of nations").

193. Mark Wheelis, *Biological Warfare Before 1914*, *in* BIOLOGICAL AND TOXIN WEAPONS: RESEARCH, DEVELOPMENT AND USE FROM THE MIDDLE AGES TO 1945, at 8, 13-15 (Erhard Geissler & John Ellis van Courtland Moon eds., 1999) [hereinafter BIOLOGICAL AND TOXIN WEAPONS]; Mark Wheelis, *Biological Warfare at the 1346 Siege of Caffa*, 8 EMERGING INFECTIOUS DISEASES 971, 973 (2002).

194. Bernhard Knollenberg, *General Amherst and Germ Warfare*, 41 MISS. VALLEY HIST. REV. 489, 493 (1954) (chronicling letters exchanged between General Jeffrey Amherst and Colonel Henry Bouquet throughout the summer of 1763).

195. FRANCIS PARKMAN, II THE OREGON TRAIL: THE CONSPIRACY OF PONTIAC 648-49 (Library of America 1991) (1853) (referencing a report from Gershou Hicks, which mentioned smallpox at Fort Pitt and among the Mingoes, Delawares and Shawanoes); Moon, *supra* note 192, at 658 (noting that "[w]hether the scheme [by Amherst] was implemented and whether it led to the smallpox epidemic among the Native Americans [in the Ohio Valley] remains a matter of historical dispute"); Wheelis, *Biological Warfare Before 1914*, *supra* note 193, at 21-24.

196. HOPKINS, *supra* note 43, at 236 (noting that many died as a result of this act).

In the twentieth century, application of the incorporeal forms of combat reached new levels of sophistication and volume. A bestiary of chemical weapons such as chlorine, phosgene, and mustard gas fouled the battlefield in World War I and claimed at least 1,300,000 casualties, including 91,000 deaths.[197] The Kaiser's Germany also tried to use primitive biological weapons as well, sending saboteurs to the United States, Russia, Argentina, and other countries to spread anthrax and glanders (another infectious animal disease) among cavalry and draft animals intended for use at the front.[198]

Remarkably, biological and chemical weapons inventories were, for the most part, idle during World War II,[199] despite the fact that all sides were ostentatiously equipped with immense arsenals of novel noxious substances,[200] and despite the fact that all parties worried perpetually that the opponent might seize an advantage by sudden initiation of the poisons.[201] The most conspicuous exception to this general pattern of reciprocal self-restraint was Japan's use of a menagerie of biological weapons, including smallpox, against eleven cities in Manchuria, and its accompanying set of macabre experiments with biological weapons conducted by the infamous Unit 731 upon at least three thousand civilians and prisoners of war.[202]

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197. CHARLES PILLER & KEITH R. YAMAMOTO, GENE WARS: MILITARY CONTROL OVER THE NEW GENETIC TECHNOLOGIES 30 (1988).

198. Wheelis, *Biological Warfare Before 1914*, *supra* note 193, at 35, 40-41; *see also* JOHN PARKER, THE KILLING FACTORY: THE TOP SECRET WORLD OF GERM AND CHEMICAL WARFARE 38 (1996) (noting the Germans' use of glanders against the Allies' horses).

199. Italy used chemical weapons against Ethiopia in 1935-36, and Japan used chemical weapons against China beginning in 1937, but the central battlefields remained largely "clean" during 1939-45. Moon, *supra* note 192, at 666-72; Yuki Tanaka, *Poison Gas: The Story Japan Would Like to Forget*, BULL. ATOMIC SCIENTISTS, Oct. 1988, at 10, 15-17 (providing examples of Japan's use of poison gases against China during the Sino-Japanese War).

200. PILLER & YAMAMOTO, *supra* note 197, at 31-32 (noting that in 1942, the United States invested $1 billion in its chemical and biological programs, and that Germany had the capacity to produce twelve thousand tons of gas per month, including the revolutionary agent tabun—the original nerve gas).

201. Donald Avery, *Canadian Biological and Toxin Warfare Research, Development and Planning, 1925-45*, *in* BIOLOGICAL AND TOXIN WEAPONS, *supra* note 193, at 190, 211-12 (noting that U.S. authorities feared that Japan might launch high-altitude balloons laden with BW against the west coast of North America); Moon, *supra* note 192, at 668-70 (noting that Britain felt especially vulnerable to a potential Nazi chemical weapons attack).

202. PETER WILLIAMS & DAVID WALLACE, UNIT 731: JAPAN'S SECRET BIOLOGICAL WARFARE IN WORLD WAR II 31-50 (1989) (describing the secret activities of Unit 731); Erhard Geissler, *Implications of Genetic Engineering for Chemical and Biological Warfare*, 1984 WORLD ARMAMENTS & DISARMAMENT SIPRI Y.B. 421, 423 (noting that "[t]hese experiments included infection with massive doses of plague, typhus, dysentery, gas gangrene, typhoid, haemorrhagic [sic] fever, cholera, anthrax, tularaemia, smallpox, tsutsugamushi and glanders"); Doug Struck, *Tokyo Court Confirms Japan Used Germ Warfare in China*, WASH. POST,

For its part, the United States sustained a major biological weapons enterprise during and after World War II.[203] President Roosevelt approved a secret biological weapons apparatus employing four thousand people, with a budget of $60 million and expansive facilities in four states.[204] Plans were developed to produce thousands of bombs laden with anthrax or botulin toxin, for use against either Germany or Japan in the late stages of the conflict.[205] Subsequently, the United States stockpiled no fewer than thirty-five different types of biological weapons, by 1969 totaling some 40,000 liters of anti-personnel agents and 45,000 BW shrapnel bombs and other devices.[206] Variola was a particular focus of attention: "We made a beautiful powder for smallpox," one U.S. biological weapons officer recalled, adding, "We used chemicals to protect it during dissemination and aerosolization" to spread the virus more effectively.[207]

Aug. 28, 2002, at A15 (reporting that a Japanese district court found that Japan had conducted germ warfare against China during World War II).

203. The United States, along with Germany and Britain, publicly promised not to use chemical weapons unless an enemy state initiated that form of combat first—a taboo that mostly held during World War II. Moon, *supra* note 192, at 669 (noting that Germany, Great Britain, and the United States pledged to abide by the Geneva Protocol in September 1939). However, these undertakings were vague as to their applicability to biological weapons, and President Roosevelt never issued a pledge clarifying the U.S. position regarding first use of BW. JUDITH MILLER ET AL., GERMS: BIOLOGICAL WEAPONS AND AMERICA'S SECRET WAR 38 (2001) ("With intelligence agencies warning that Tokyo and Berlin had biological weapons, Washington began to mobilize against germ attacks in 1942. President Franklin D. Roosevelt publicly denounced the exotic arms of America's foes as 'terrible and inhumane,' even while preparing to retaliate in kind.").

204. STEPHEN ENDICOTT & EDWARD HAGERMAN, THE UNITED STATES AND BIOLOGICAL WARFARE: SECRETS FROM THE EARLY COLD WAR AND KOREA 31 (1998); John Ellis van Courtland Moon, *US Biological Warfare Planning and Preparedness: The Dilemmas of Policy*, *in* BIOLOGICAL AND TOXIN WEAPONS, *supra* note 193, at 215; *see also* ED REGIS, THE BIOLOGY OF DOOM: THE HISTORY OF AMERICA'S SECRET GERM WARFARE PROJECT 25-32 (1999) (describing the collaboration between British scientists and George W. Merck, Roosevelt's head of the War Research Service).

205. Moon, *U.S. Biological Warfare Planning*, supra note 204, at 248-49; Moon, *supra* note 192, at 670 (stating that of the many potential BW tested, only anthrax and botulinus toxin were actively developed).

206. JULIAN PERRY ROBINSON, II THE PROBLEM OF CHEMICAL AND BIOLOGICAL WARFARE: CB WEAPONS TODAY 234 (1973); *see also* Susan Wright, *Evolution of Biological Warfare Policy: 1945-1990*, *in* PREVENTING A BIOLOGICAL ARMS RACE 26, 34 (Susan Wright ed., 1990); Martin Enserink, *Secret Weapons Tests' Details Revealed*, 298 SCI. 513, 513-14 (2002) (discussing the release of Department of Defense documents, which detail tests involving pathogens and toxic chemicals).

207. Shannon Brownlee, *Clear and Present Danger*, WASH. POST, Oct. 28, 2001, Magazine, at W08 (quoting Bill Patrick, a former bioweapons pioneer who worked at Fort Detrick, Maryland); *see also* MILLER ET AL., *supra* note 203, at 59-60 (stating that scientists at Fort Detrick developed a method to turn freeze-dried variola into a fine powder which could be placed in small aerosol generators or atomizers).

B. *Legal Regulation of Biological Weapons*

At the same time that various armies around the world were planning, procuring, and practicing for this widely-anticipated biological and chemical warfare, public opinion and the international legal community were uniting in opposition. A profound loathing for these poisons is of ancient provenance; the same cultures that conveyed storied illustrations of the use of CBW also generated the beginnings of a legal regime restraining their application. Indian, Greek, and Roman codes all abhorred these unconventional weapons,[208] and international law publicists in the seventeenth and eighteenth centuries likewise pronounced them beyond the pale of civilized conduct.[209]

A fistful of treaties—the 1868 Declaration of St. Petersburg,[210] the 1874 Declaration of Brussels,[211] and the 1899 and 1907 Hague Conventions[212]—continued the international legislation against CBW, and post-World War I agreements further deepened that global consensus.[213] The key instrument, the 1925 Geneva Protocol,[214] re-

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208. *See* Moon, *supra* note 192, at 657 (stating that "[b]y the end of the classical period, the prohibition against poison was a principle of customary international law").

209. *See id.* at 658.

210. Declaration Renouncing the Use, in Time of War, of Explosive Projectiles Under 400 Grammes Weight (St. Petersburg Declaration), Dec. 11, 1868, 18 Martens (ser. 1) 474, *reprinted in* A MANUAL ON INTERNATIONAL HUMANITARIAN LAW AND ARMS CONTROL AGREEMENTS 85 (M. Cherif Bassiouni ed., 2000).

211. Project of an International Declaration Concerning the Laws and Customs of War, August 27, 1874, 4 Martens (ser. 2) 219, *reprinted in* A MANUAL ON INTERNATIONAL HUMANITARIAN LAW AND ARMS CONTROL AGREEMENTS, *supra* note 210, at 87.

212. Convention (II) with Respect to the Laws and Customs of War on Land and Its Annex: Regulations Concerning the Laws and Customs of War on Land, July 29, 1899, 26 Martens (ser. 2) 949, *reprinted in* A MANUAL ON INTERNATIONAL HUMANITARIAN LAW AND ARMS CONTROL AGREEMENTS, *supra* note 210, at 93; Convention (IV) Respecting the Laws and Customs of War on Land and Its Annex: Regulations Concerning the Laws and Customs of War on Land, October 18, 1907, 3 Martens (ser. 3) 461-503, *reprinted in* A MANUAL ON INTERNATIONAL HUMANITARIAN LAW AND ARMS CONTROL AGREEMENTS, *supra* note 210, at 103. This declaration, containing the same language as the 1899 "Laws and Customs of War on Land," was signed by the countries that were later to become the principal belligerents in World War I. Article 22 of the 1907 treaty affirms that "[t]he right of belligerents to adopt means of injuring the enemy is not unlimited." *Id.* at 105. Article 23 continues, "[i]n addition to the prohibitions provided by special Conventions, it is especially forbidden . . . to employ poison or poisoned weapons." *Id.* at 106.

213. Treaty of Peace Between the Allied and Associated Powers and Germany (Treaty of Versailles), June 28, 1919, art. 171, 2 Bevans 43, 119. The treaty prohibited "the manufacture and importation" of "asphyxiating, poisonous or other gases and all analogous liquids, materials or devices" by Germany. *Id.*

Similar provisions were inserted into the post-war peace treaties with other defeated countries. *See* Treaty in Relation to the Use of Submarines and Noxious Gases in Warfare, Feb. 6, 1922, 25 L.N.T.S. 202. Under Article 5 of the Five-Power Washington Naval Limitation Treaty, the parties observed that "the use of asphyxiating, poisonous or other gases, and all analogous liquids, materials or devices, having been justly condemned by the gensponded to the horror of battlefield toxins by prohibiting "the use in war of asphyxiating, poisonous or other gases, and of all analogous liquids, materials or devices"[215] and recording the parties' further undertaking "to extend this prohibition to the use of bacteriological methods of warfare."[216]

Unfortunately, the Geneva Protocol—still in force for 132 parties, including the United States[217]—hardly constitutes a complete solution to the problem of CBW for several reasons. First, that treaty bans only the *use* in warfare; it does not inhibit parties' development, possession, deployment or proliferation of the regulated arms.[218] In fact, through a series of reservations, countries mostly retained the right to apply biological and chemical weapons in retaliation, if some other country violated the taboo first.[219] Large CBW arsenals, therefore,

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eral opinion of the civilized world and a prohibition of such use having been declared in treaties to which a majority of the civilized Powers are parties" and affirmed their assent to such a prohibition. Howard S. Levie, *Humanitarian Restrictions on Chemical and Biological Warfare*, 13 U. TOL. L. REV. 1192, 1994-95 (1982). The United States Senate gave its advice and consent to ratification of this treaty without a single dissenting vote, but the treaty never entered into force, because France declined to ratify it due to an unrelated disagreement over the provisions governing submarines. Moon, *supra* note 192, at 664.

214. Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, June 17, 1925, 26 U.S.T. 571, 94 L.N.T.S. 65 [hereinafter Geneva Protocol].

215. *Id.* at 575, 94 L.N.T.S. at 67.

216. *Id.*, 94 L.N.T.S. at 69.

217. The United States signed the Geneva Protocol in 1925, but did not ratify it for fifty years. *See* W. Hays Parks, *Classification of Chemical Biological Warfare*, 13 U. TOL. L. REV. 1165, 1170 (1982) (noting that intense lobbying from CW enthusiasts scuttled the Geneva Protocol in the U.S. Senate, where it lingered until President Truman withdrew it in 1951). The treaty was re-submitted by President Nixon and ultimately consented to by the Senate and ratified by President Ford in 1975 following a protracted debate about the coverage of specialized chemicals known as herbicides and riot-control agents. *Id.*

218. *See* Geneva Protocol, *supra* note 214, 26 U.S.T. at 571, 94 L.N.T.S. at 67. The prohibition against the *first* use of chemical weapons probably ripened into a norm of customary international law at some point in the twentieth century and thus became binding even upon states that did not adhere to the Geneva Protocol or any other treaty incorporating the rule. Such a customary norm "results from a general and consistent practice of states followed by them from a sense of legal obligation." RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES § 102 (1986). It may arise from treaties that are "designed for adherence by states generally," and are in fact widely accepted, but it is not binding upon a state that consistently demonstrates its dissent from the putative rule. *Id.* § 102 cmt. i; *see also* Parks, *supra* note 217, at 1167 (noting agreement among legal scholars that the prohibition against first use of CW in war has become a part of customary international law); *cf.* Harry H. Almond, Jr., *Control over Chemical Weapons—Personal Perspectives on the Emerging United States Position*, 13 U. TOL. L. REV. 1203, 1205 (1982)).

219. A reservation is a unilateral statement through which a state "purports to exclude or modify the legal effect" of selected provisions of a treaty. Vienna Convention on the Law of Treaties, *entry into force*, Jan. 27, 1980, 1155 U.N.T.S. 331, 333. *See* Moon, *supra* note 192, at 664 (quoting the French reservation to the Geneva Protocol, which states that the

could be sustained and expanded indefinitely.[220] Second, the treaty incorporates no mechanisms for verifying or compelling parties' compliance with the undertakings.[221] There are no provisions for inspections, data reporting, or the like, nor are there institutions for resolving the inevitable disputes about treaty interpretation and application or for enforcing the obligations against violators.[222]

Third, vocabulary employed in the Geneva Protocol speaks inartfully of banning "bacteriological" methods of warfare.[223] Today, we know that the complex world of microorganisms includes many creatures besides bacteria that are of potential biological weapons application, such as viruses, fungi, and rickettsia.[224] While the parties to the Geneva Protocol have subsequently affirmed that its terms apply fully to all manner of microorganisms,[225] regardless of the scientific catego-

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treaty would "cease to be binding" on France in its dealings with "any enemy State whose armed forces or whose allies fail to respect the prohibitions laid down in the Protocol").

220. Parks, *supra* note 217, at 1170-71 (noting that due to the multiplicity of reservations, the Geneva Protocol did not develop into a prohibition against possession or use of chemical weapons *per se*). The threat of retaliation in kind against a state that had initiated CW use became, in effect, the treaty's primary enforcement mechanism, thereby perhaps actually encouraging some countries to maintain a CW capability.

221. *Id.*

222. Most modern arms control treaties regarding nuclear, chemical, and other weapons have come to incorporate elaborate provisions regarding verification of compliance because American political leaders insisted upon exacting, legally-binding procedures to provide assurance that each side fulfills its undertakings. In fact, the majority of the text of most arms control treaties is composed of definitions, counting rules, inspection procedures, and the like. The basic "ban" provisions of the treaty are usually easier to negotiate and to draft than are the mechanisms for deterring, detecting, and correcting violations. *See generally* GRAHAM, *supra* note 38 (discussing the negotiations for several disarmament agreements).

223. Geneva Protocol, *supra* note 214, 26 U.S.T. at 575, 94 L.N.T.S. at 69. In the Geneva Protocol negotiations, the delegate from Poland argued that future bacteriological warfare could be even more inhumane than chemical warfare; this was the first occasion upon which an international instrument explicitly incorporated what we now recognize as a distinction between BW and CW. Jerzy Witt Mierzejewski & John Ellis van Courtland Moon, *Poland and Biological Weapons*, *in* BIOLOGICAL AND TOXIN WEAPONS, *supra* note 193, at 65-67; Moon, *supra* note 192, at 664.

224. Viruses are generally much smaller and simpler than bacteria, possessing fewer of the hallmark characteristics of life forms; they were discovered later than bacteria and were largely unknown at the time of the negotiation of the Geneva Protocol. JOSEPH CIRINCIONE, DEADLY ARSENALS: TRACKING WEAPONS OF MASS DESTRUCTION 46 (2002). Rickettsias are another heterogeneous group of usually pathogenic microorganisms infecting arthropods, mammals, and others, causing diseases such as Rocky Mountain spotted fever. Emilio Weiss, *Rickettsias*, *in* 3 ENCYCLOPEDIA OF MICROBIOLOGY 585, 585 (Joshua Lederberg ed., 1992).

225. Moon, *supra* note 192, at 664-65.

ries discovered after 1925, the language employed by the drafters is not, on its face, so comprehensive.[226]

C. *Biological Weapons Convention*

Diplomats therefore undertook persistent efforts to extend or elaborate the Geneva Protocol in various ways, but these mostly stalled for much of the inter-war and immediate post-World War II eras.[227] In 1969, the United States injected fresh energy into the subject when President Richard M. Nixon unilaterally pledged to renounce all forms of offensive biological warfare, to destroy the existing U.S. stockpile of such weapons, and to close or convert to other purposes all facilities that had previously been used in the production of the despised armaments.[228] Within two years, the United States and the

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226. Geissler, *supra* note 202, at 435-36 (arguing that even though the scientific meaning of the term "bacteriological" is narrower than the term "biological," it has always been accepted that in the legal context of the Geneva Protocol, the two words are exact synonyms). The United Nations General Assembly likewise concluded that "the Geneva Protocol embodies the generally recognized rules of international law prohibiting the use in international armed conflicts of all biological and chemical methods of warfare, regardless of any technical developments." *Question of Chemical and Bacteriological (Biological) Weapons*, G.A. Res. 2603-A, U.N. GAOR, 24th Sess., Supp. No. 30, at 16-17, U.N. Doc. A/RES/2603A (XXIV) (1969).

227. For many years, issues about the enhanced regulation of biological and chemical weapons were ensnared in a larger debate about the pursuit of "general and complete disarmament," which would have required articulation of a full-scale, time-specific program for dismantling *all* categories of weapons before any concrete steps could be undertaken regarding any particular class of arms. ACDA TREATY BOOK, *supra* note 26, at 3. Only after protracted delay did participants grasp the virtue in seizing whatever opportunities might be available for immediate incremental progress in regulating selected categories of arms. Even after that, however, countries disagreed about the wisdom of treating biological weapons separately from chemical weapons. Many worried that extending the Geneva Protocol to impose tighter limits on only one subset of weapons would implicitly license even greater competition in the other. Eventually, pragmatists were attracted to the idea of isolating whatever portions of the overall disarmament problem appeared amenable to prompt resolution—and for a variety of reasons, control of biological weapons was "ripe" far sooner than of chemical weapons. *See* Lawler, *supra* note 191, at 1224-26 (discussing the United Kingdom's position that chemical and biological methods of warfare be dealt with separately, and that a treaty prohibiting biological methods be concluded swiftly) (citing Official Records of the Disarmament Commission, Supplement for 1967 and 1968, U.N. Doc. DC/231 at 39, Annex I (1968)); *see also* Flowerree, *supra* note 24, at 1005 (stating that on August 16, 1971 the UN General Assembly endorsed the BWC, which addressed only biological and toxic weapons); Aida Luisa Levin, *Historical Outline*, *in* STRENGTHENING THE BIOLOGICAL WEAPONS CONVENTION BY CONFIDENCE-BUILDING MEASURES 5, 5-7 (Erhard Geissler ed., 1990) (noting that the issue of whether to deal with biological and chemical weapons separately was one of the foremost on the agenda at the 1970 session of the Conference of the Committee on Disarmament (CCD)).

228. Richard Nixon, Statement on Chemical and Biological Defense Policies and Programs, *in* PUBLIC PAPERS OF THE PRESIDENTS OF THE UNITED STATES: RICHARD NIXON 1969, at 968 (1971). President Nixon declared that "[m]ankind already carries in its own hands

Soviet Union produced a consensus draft of a suitable treaty to internationalize those commitments,[229] and the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (commonly referred to as the Biological Weapons Convention or BWC)[230] was formally opened for signature in 1972 and entered into force in 1975.[231] Today, the treaty has attracted 144 parties, including all five permanent members of the United Nations Security Council, as well as most of the countries of significant proliferation concern, such as Iran, Iraq, Libya, and North Korea.[232]

The BWC fixes many of the shortcomings of the Geneva Protocol. The newer instrument is much more expansive in its verbs (parties

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too many of the seeds of its own destruction," and that "[b]iological weapons have massive, unpredictable and potentially uncontrollable consequences." *Id.* at 968-69. The United States, therefore, renounced its use of biological agents, confined its biological research to defensive measures, and disposed of its existing stocks of bacteriological weapons. *Id.* at 968-69.

Also on November 25, 1969, Henry Kissinger issued National Security Decision Memorandum 35, elaborating the policy by declaring: "The United States bacteriological/biological programs will be confined to research and development for defensive purposes (immunization, safety measures, et cetera). This does not preclude research into those offensive aspects of bacteriological/biological agents necessary to determine what defensive measures are required." National Security Decision Memorandum 35 from Henry Kissinger to the Vice President et al. (Nov. 25, 1969), *in* PREVENTING A BIOLOGICAL ARMS RACE, *supra* note 206, at 403-04. Following the American declaration, several other countries followed suit, with Canada, Sweden, and Great Britain announcing that they possessed no biological weapons and had no plans to create any. Flowerree, *supra* note 24, at 1005.

229. The primary forum for the negotiations was the Conference of the Committee on Disarmament, a United Nations affiliate charged with responsibility for articulating arms control agreements. In reality, the critical bargaining was conducted bilaterally between the United States and the Soviet Union, who developed and then tabled separate but identical drafts of a BW treaty. The document was then debated and approved by the other participating countries. Flowerree, *supra* note 24, at 1005; Lawler, *supra* note 191, at 1228-31.

230. Biological Weapons Convention, *supra* note 23, 26 U.S.T. 583, 1015 U.N.T.S. 163. The U.S. Senate gave unanimous consent to ratification of the BWC. Flowerree, *supra* note 24, at 1005.

231. ACDA TREATY BOOK, *supra* note 26, at 124. President Richard Nixon hailed the BWC as "the first international agreement since World War II to provide for the actual elimination of an entire class of weapons from the arsenals of nations." *Id.* at 122. The Senate Foreign Relations Committee somewhat delayed consideration of the BWC in order to clarify outstanding issues regarding the Geneva Protocol at the same time. *Id.* However, President Gerald Ford signed the two instruments of ratification simultaneously. *Id.*

232. FIFTH REVIEW CONFERENCE OF THE STATE PARTIES TO THE BWC CONVENTION, LIST OF STATES PARTIES TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION, AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION (2002), *available at* www.brad.ac.uk/acad/sbtwc/btwc/convention/documents/btwcsps.pdf (last visited Apr. 5, 2003). Notable non-party states include Israel, Egypt, Syria, and Sudan. *See id.*

promise "never in any circumstances to develop, produce, stockpile, or otherwise acquire or retain" the relevant weapons,)[233] its nouns (it proscribes "[m]icrobial or other biological agents, or toxins whatever their origin or method of production"),[234] and its adjectives (it uses the modifiers "biological" and "bacteriological" interchangeably, to help ensure that all manner of microscopic organisms are encompassed).[235]

At the same time, the BWC, like its predecessor, still suffers from profound institutional shortcomings in the vital areas of verification (lacking effective mechanisms for assuring a party that its treaty partners are complying with their obligations)[236] and enforcement (omitting sufficient structures for adequately investigating allegations of violations and resolving disputes).[237]

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233. Biological Weapons Convention, *supra* note 23, 26 U.S.T. at 587, 1015 U.N.T.S. at 166. The BWC does not explicitly ban "use" of the weaponry, as the Geneva Protocol had, since a country could not plausibly use biological arms without violating the prohibitions against possession. *Id.*; ACDA TREATY BOOK, *supra* note 26, at 9 (describing the Geneva Protocol).

234. Biological Weapons Convention, *supra* note 23, 26 U.S.T. at 587, 1015 U.N.T.S. at 166.

235. *Id.* at 590, 1015 U.N.T.S. at 167. Article I of the treaty specifies "microbial or other biological agents," without citing "bacteriological" (as the document's title does), but article X reverts to the phrase "bacteriological (biological)" in describing the international exchange of scientific and technological information. *Id.* at 587, 590, 1015 U.N.T.S. at 166, 167.

236. *See* Tibor Tóth et al., *Verification of the BWC, in* CONTROL OF DUAL-THREAT AGENTS: THE VACCINES FOR PEACE PROGRAMME 67, 67-76 (Erhard Geissler & John P. Woodall eds., 1994) (acknowledging that the BWC has no provision for monitoring or verification, and evaluating the potential verification measures reviewed by an Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint (VEREX) in 1991 and VEREX II-IV through 1994); *see also* NICHOLAS A. SIMS, THE EVOLUTION OF BIOLOGICAL DISARMAMENT 82-118 (2001) (examining the treatment of verification and strengthening measures throughout the history of the BWC). Most other modern arms control instruments have incorporated elaborate mechanisms for exchanges of data regarding treaty-limited items, for various types of on-site inspections, and for other "transparency" measures to enhance confidence in other parties' compliance. *See* Thilo Marauhn, *Routine Verification Under the Chemical Weapons Convention, in* THE NEW CHEMICAL WEAPONS CONVENTION—IMPLEMENTATION AND PROSPECTS 219 (Michael Bothe et al. eds., 1998) (stating that "[r]outine verification is the primary means to ensure compliance under the [Chemical Weapons] Convention, while challenge inspections and investigations of alleged use serve to fill the remaining gaps in the overall verification system").

237. *See* SIMS, *supra* note 236, at 23-25 (explaining that the BWC's compliance regime is not the equivalent of true verification). BWC parties commit themselves "to consult one another and to cooperate in solving any problems which may arise in relation to the objective of, or in the application of the provisions of, the Convention." Biological Weapons Convention, *supra* note 23, 26 U.S.T. at 588, 1015, U.N.T.S. at 167. Further, any party may lodge a complaint with the United Nations Security Council if it finds that another party has acted in breach of its BWC obligations, and parties undertake to cooperate in carrying

Moreover, the BWC struggles uphill against the persistent phenomenon of "dual capability."[238] That is, many of the same substances, equipment, and procedures that are relevant to biological weapons programs are simultaneously integral to a wide range of commercial applications in diverse sectors of the global civilian economy from pharmaceuticals to plastics to foodstuffs.[239] Allowing those myriad peaceful invocations of biotechnology, while constraining their military crossovers is a trick the treaty drafters were unable to accomplish with perfect precision.[240] In addition, the treaty allows parties to undertake *defensive* military biological inquiries such as developing improved BW sensors, decontamination procedures, and gas masks, even while acknowledging that the dividing line between offensive and defensive employments is obscure and ephemeral at best.[241]

In the case of smallpox, for example, the BWC's permission for retention of the pernicious virus for "prophylactic, protective, or other peaceful purposes"[242] would enable a party to retain at least small quantities of variola and to undertake research upon it that might be susceptible to being secretly twisted to a one-sided military advantage.[243] Any benign innovation, such as an improved vaccine or

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out any investigation that the Security Council initiates. *Id.* at 588-89, 1015 U.N.T.S. at 167. In contrast, the Chemical Weapons Convention creates a new international organization with significant verification and dispute-resolution responsibilities. *See* Andrea DeGuttry, *The Organization for the Prohibition of Chemical Weapons, in* THE NEW CHEMICAL WEAPONS CONVENTION—IMPLEMENTATION AND PROSPECTS, *supra* note 236, at 119, 121-22 (discussing the creation and powers of the Organization for the Prohibition of Chemical Weapons under the Chemical Weapons Convention).

238. Barbara Hatch Rosenberg, *Allergic Reaction: Washington's Response to the BWC Protocol*, ARMS CONTROL TODAY, July-Aug. 2001, at 3 (addressing the issue of dual-use equipment and facilities while arguing that the U.S. should be advocating a stronger verification protocol).

239. *See id.* (explaining that many of the same products and procedures can be used for peaceful or military purposes).

240. Erhard Geissler, *Arms Control, Health Care and Technology Transfer Under the Vaccines for Peace Programme, in* CONTROL OF DUAL-THREAT AGENTS: THE VACCINES FOR PEACE PROGRAMME, *supra* note 236, at 10-16, 23 (acknowledging that while the BWC permits research, development and production of 'dual-threat' agents for peaceful purposes, it is difficult to discern those operations from others which may have an offensive objective).

241. *See* Susan Wright, *Biowar Treaty in Danger*, 47 BULL. ATOMIC SCIENTISTS, Sept. 1991, at 36-37 (addressing the BWC's ambiguity with regard to defensive and offensive biological agents research); *see also* MILLER ET AL., *supra* note 203, at 84 (stating that the U.S. military's "defensive" programs in 1980-86 supported scores of research projects aimed at making novel pathogens, increasing toxin production, defeating vaccines, inhibiting diagnosis, and outwitting protective drugs).

242. Biological Weapons Convention, *supra* note 23, 26 U.S.T. at 587, 1015 U.N.T.S. at 166.

243. Geissler, *supra* note 240, at 11 (citing testimony of V. Sidel, past president of the American Public Health Association, on the subject of the difficulty inherent in separating defensive and offensive programs).

effective antiviral medications that might enable one country to defend itself better against its neighbor's offensive BW use might, after all, also become a basis for a treaty violator to seek to use the improved capabilities to sponsor its own BW aggression with less fear of retaliation in kind.[244]

D. *Protocol Negotiations*

In response to those perceived shortcomings, BWC parties have undertaken still further deliberations and negotiations, now stretching over more than a decade, to amend that treaty too.[245] A difficult balancing act is required: any steps that provide greater "transparency" for military-related BW activities will also carry the inherent danger of jeopardizing legitimate defensive secrets as well.[246] Each participating government may therefore be schizophrenic about greater openness. Partly, it will seek greater insight into the BW-related activities of its neighbors and potential rivals, but partly it will also seek to shield from foreign oversight any of its own defensive BW-related military programs that might, if kept secret, enhance its ability to overcome an illegal BW attack that might one day be launched against it.[247] Private industry, too, has a great deal at stake in these negotiations: private pharmaceutical companies and others on the cutting edge of innovative biological technology might find their proprietary production techniques and other confidential business infor-

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244. *See id.* ("'To mount a program specifically for medical "defense" against such [dual-threat] agents would appear to others in the world to be simply a continuation of an arms race in these weapons'") (quoting Sidel's testimony before the Committee on Governmental Affairs and its Permanent Subcommittee on Investigations, U.S. Senate (Feb. 9, 1989)).

245. Tóth, *supra* note 236, at 67-68. Parties to the BWC have long considered a variety of proposals, floated in a range of negotiating fora, for different types of supplements or amendments that would strengthen, clarify, or extend the treaty to deal with its perceived shortcomings. *Id.* at 68. A series of voluntary "politically binding" measures proved inadequate over the years, as too many countries declined to provide the full and timely reports suggested by reformers, so the effort progressed toward the articulation of a legally binding instrument that would require treaty parties to supply additional information and access, to better ensure the transparency of their BW-related activities. *See* Graham S. Pearson, *The Protocol to the Biological Weapons Convention Is Within Reach*, ARMS CONTROL TODAY, June 2000, at 15; Nicholas A. Sims, *The BTWC in Historical Perspective: From Review to Strengthening Processes to an Integrated Treaty Regime*, DISARMAMENT F., No. 4 2000, at 19, 20-22, *available at* http://www.unidir.ch/pdf/articles/pdf-art109.pdf (last visited Apr. 2, 2003).

246. *See* Nicholas A. Sims, *Control and Co-operation in Biological Defence Research: National Programmes and International Accountability, in* CONTROL OF DUAL-THREAT AGENTS: THE VACCINES FOR PEACE PROGRAMME, *supra* note 236, at 56, 61-63 (discussing Canada's introduction of the concept of transparency mechanisms at the Third Review Conference in 1991 and stating that governments would need reassurance that there is no threat to their security).

247. *See id.* at 61.

mation in danger of exposure via intrusive data reporting requirements or on-site inspections.[248]

With all that complexity, it should be no surprise that the negotiations to strengthen the BWC have crept along at only a snail's pace.[249] Indeed, it may be more remarkable that any progress at all has been registered. For many years, the United States government resisted convening any formal bargaining sessions on the basis that it would be impossible to craft a suitable compromise.[250] Still, by the summer of 2001, it appeared that a solution might be within reach: a lengthy, complex, and delicately-balanced package of compromises was emerging from the negotiations.[251] The draft protocol fully satisfied almost no one, but many countries and outside observers grudgingly conceded that it might make a modest contribution to enhanced confidence in parties' BWC compliance at an acceptable cost.[252]

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248. *See* Rosenberg, *supra* note 238, at 3 (stating that the reasons for U.S. rejection of proposed provisions include the threat to commercial proprietary information); FED'N OF AM. SCIENTISTS, PERSPECTIVES ON THE BWC COMPLIANCE REGIME: ISSUES AFFECTING INDUSTRY 1988, http://www.fas.org/bwc/papers/perspectives.html (last visited Apr. 5, 2003).

249. *See* Levin, *supra* note 227, at 10-14 (tracing the history of the BWC); Sims, *supra* note 245, at 19 (characterizing the history of the BWC as without "a simple linear progress ever onward and upward, but . . . complicated").

250. Levin, *supra* note 227, at 10. Indeed, the United States was unwilling to refer to the negotiations as an effort to produce a "verification protocol" for the BWC, because it has concluded that true "verification" of compliance with the terms of the treaty can never be achieved. *See* Freedberg & Serafini, *supra* note 178, at 809. Instead, the goal was described in more modest terms, as an attempt to draft a "transparency" instrument that will incorporate a variety of "confidence-building measures," which will collectively enable countries to feel somewhat more reassured about other states' behavior, but which will not approach the high level of certainty demanded in most other arms control applications. *See* Sims, *supra* note 246, at 61-62; Erhard Geissler, *Agreed Measures and Proposals to Strengthen the Convention*, *in* STRENGTHENING THE BIOLOGICAL WEAPONS CONVENTION BY CONFIDENCE-BUILDING MEASURES, *supra* note 227, at 43.

251. Seth Brugger, *Executive Summary of the Chairman's Text*, ARMS CONTROL TODAY, May 2001, at 10. The draft protocol totals 210 pages, comprising 30 articles, 3 annexes, and 9 appendices. *Id.* It incorporates a tiered system of declarations about states' BW-related activities, different types of on-site inspections and visits, a new international organization to implement the accord, penalties for non-compliance, and a program of international scientific and technical cooperation and assistance. *Id.*

252. Marie Isabelle Chevrier, *A Necessary Compromise*, ARMS CONTROL TODAY, May 2001, at 14-15, 33; Robert P. Kadlec, *First, Do No Harm*, ARMS CONTROL TODAY, May 2001, at 16-17, 32; James F. Leonard, *An Essential First Step*, ARMS CONTROL TODAY, May 2001, at 18-19; Michael Moodie, *Building on Faulty Assumptions*, ARMS CONTROL TODAY, May 2001, at 20-23; John Steinbruner et al., *A Tough Call*, ARMS CONTROL TODAY, May 2001, at 23-24; Alan P. Zelicoff, *An Impractical Protocol*, ARMS CONTROL TODAY, May 2001, at 25-27. *See generally* HENRY L. STIMSON CTR., COMPLIANCE THROUGH SCIENCE; US PHARMACEUTICAL INDUSTRY EXPERTS ON A STRENGTHENED BIOWEAPONS NONPROLIFERATION REGIME (2002) (noting that industry experts concluded that the draft protocol would not have sufficient inspection powers to detect all violations, but that several components of the proposed treaty would

The Bush administration, however, suddenly spiked the incipient deal.[253] The draft protocol, according to the United States, was irretrievably defective in two contrasting dimensions. First, it failed to establish a sufficiently robust inspection regime to detect, and thereby to deter, potential cheating by other countries.[254] Second, the intrusions it did warrant would be unacceptably costly in compromising U.S. private industry's trade secrets and the national government's military secrets.[255] Instead, the United States proposed an alternative series of reforms, including reciprocal commitments to strengthen each party's national legislation prohibiting BW-related activities and establishment of a regime for international inspections of suspicious outbreaks of disease.[256] By the end of 2001, however, the United States also unilaterally proposed terminating the protocol negotiations altogether—a surprise move that threw the diplomatic community into stark confusion about the future course of BWC proceedings.[257]

E. Soviet and Russian BW Programs

The Soviet Union, throughout the cold war era and even afterward, compiled and maintained the world's largest, most ambitious

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be useful), *available at* http://www.stimson.org/cbw/pdf/ComplianceScience.pdf (last visited Apr. 5, 2003).

253. *See* Rebecca Whitehair & Seth Brugger, *BWC Protocol Talks in Geneva Collapse Following U.S. Rejection*, ARMS CONTROL TODAY, Sept. 2001, at 26 (reporting statement by Ambassador Donald Mahley, the head of the U.S. Ad Hoc Delegation, rejecting the draft protocol).

254. *See id.*

255. *See id.*; GRAHAM S. PEARSON ET AL., STRENGTHENING THE BIOLOGICAL CONVENTION REVIEW CONFERENCE PAPER NO. 4, THE US STATEMENT AT THE FIFTH REVIEW CONFERENCE: COMPOUNDING THE ERROR IN REJECTING THE COMPOSITE PROTOCOL 1 (2002), *available at* http://www.brad.ac.uk/acad/sbtwc/briefing/RCP_4.pdf (last visited Apr. 5, 2003).

256. *See* HENRY L. STIMSON CTR., *supra* note 252, at 11-12; Seth Brugger, *U.S. Presents Alternatives to BWC Protocol at Review Conference*, ARMS CONTROL TODAY, Dec. 2001, at 22; Jonathan B. Tucker & Raymond A. Zilinskas, *Assessing U.S. Proposals to Strengthen the Biological Weapons Convention*, ARMS CONTROL TODAY, Apr. 2002, at 10; John R. Bolton, *Remarks to the Fifth Biological Weapons Convention Review Conference Meeting* (Nov. 19, 2001), http://www.state.gov/t/us/rm/janjuly/6231.htm (last visited Apr. 5, 2003); ARMS CONTROL ASS'N, BRIEFING PAPER ON THE STATUS OF BIOLOGICAL WEAPONS NONPROLIFERATION (2002), http://www.armscontrol.org/factsheets/bwissuebrief.asp (last visited Apr. 5, 2003).

257. Seth Brugger, *BWC Conference Suspended After Controversial End*, ARMS CONTROL TODAY, Jan.-Feb. 2002, at 34 (noting that the U.S. was the only country to advocate abandoning the protocol negotiations); NICHOLAS A. SIMS, STRENGTHENING THE BIOLOGICAL WEAPONS CONVENTION REVIEW CONFERENCE PAPER NO. 5, RETURN TO GENEVA: THE NEXT STAGE OF THE BTWC FIFTH REVIEW CONFERENCE 2 (2002), *available at* http://www.brad.ac.uk/acad/sbtwc/briefing/RCP_5.pdf (last visited Apr. 5, 2003); ARMS CONTROL ASS'N, *supra* note 256, *available at* http://www.armscontrol.org/factsheets/bwissuebrief.asp.

biological weapons program,[258] a campaign in which smallpox was always singled out as an element of special prominence.[259]

Two related, somewhat redundant, and often feuding bureaucracies undertook overlapping BW activities for the U.S.S.R. First, the Ministry of Defense sponsored the full range of military biological and chemical programs and succeeded in winning sufficient funds to assemble the world's largest, most capable CBW corps, equipped with the most sophisticated offensive and defensive equipment.[260] The U.S.S.R. integrated those unconventional capabilities into its standard war-fighting doctrine and training routines far more effectively and comprehensively than did Western countries.[261]

Second, a shadow Soviet BW institution—created in the fateful year 1973[262]—proceeded in even greater secrecy under the cover of a civilian enterprise, "Biopreparat,"[263] which was ostensibly devoted to medical and pharmaceutical investigations.[264] The Biopreparat archipelago embraced fifty facilities across the country, employing approximately thirty thousand scientists and technicians on weapons programs, and commanding a budget upwards of $1 billion annually.[265]

Ken Alibek, a 1992 defector to the West who had formerly served as Biopreparat's deputy director, maintains that the Soviets considered smallpox to be "their No. 1 strategic weapon."[266] Although the

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258. KEN ALIBEK & STEPHEN HANDELMAN, BIOHAZARD, at x (1999).

259. *See id.* at 19 (noting the caches of smallpox stored throughout the Soviet Union, intended for use against the United States).

260. *Id.* at 40-41.

261. *Id.* at 160, 164, 295-300 (stating that U.S.S.R. microbiologists developed novel strains of antibiotic-resistant anthrax and plague weapons and numerous Soviet government organizations each played a role in developing biological weapons); MILLER ET AL., *supra* note 203, at 165-82; MONTEREY INST. OF INT'L STUDIES, CTR. FOR NONPROLIFERATION STUDIES OCCASIONAL PAPER NO. 9, THE 1971 SMALLPOX EPIDEMIC IN ARALSK, KAZAKHSTAN, AND THE SOVIET BIOLOGICAL WARFARE PROGRAM (Jonathan B. Tucker & Raymond A. Zilinskas, eds. 2002), *available at* http://cns.miis.edu/pubs/opapers/op9/op9.pdf (last visited Apr. 5, 2003); JULIAN PERRY ROBINSON ET AL., II THE PROBLEM OF CHEMICAL AND BIOLOGICAL WARFARE 161-84 (1973).

262. ALIBEK & HANDELMAN, *supra* note 258, at 41.

263. *Id.*

264. *See* TUCKER, *supra* note 95, at 145; David Hoffman, *Deadly Germs from Cold War: Soviet-Era Reveals Extent of Biological Weapons Research*, WASH. POST, June 7, 2000, at A24.

265. *See* ALIBEK & HANDELMAN, *supra* note 258, at 41-43; TUCKER, *supra* note 95, at 139-65; Christopher J. Davis, *Nuclear Blindness: An Overview of the Biological Weapons Programs of the Former Soviet Union and Iraq*, 5 EMERGING INFECTIOUS DISEASES 509 (1999); Jonathan B. Tucker, *Biological Weapons in the Former Soviet Union: An Interview with Dr. Kenneth Alibek*, NONPROLIFERATION REV., Spring-Summer 1999, at 1, 4 [hereinafter *Biological Weapons in the Former Soviet Union*].

266. Wendy Orent, *The End of the Trail for Smallpox?*, L.A. TIMES, Aug. 2, 1998, at M2.

far-flung BW empire explored numerous other biological agents too—including anthrax, plague, Ebola, tularemia, and many others—variola was always an item of special Soviet fascination and enterprise, predating even the WHO's successful global smallpox eradication campaign and persisting long after the BWC had rendered any such offensive weapons programs patently illegal.[267]

Over a period of decades, Moscow succeeded in accumulating a massive inventory of ready-to-use smallpox weapons. Some twenty tons of a novel liquid agent were stockpiled, and continuous production, to repeatedly refresh materials of short shelf-life, was undertaken at the Ministry of Defense installation at Zagorsk.[268] Several of the largest, most powerful Soviet intercontinental ballistic missiles, the SS-18s, were dedicated to the smallpox BW mission.[269] Each was capable of depositing 375 kilograms of viral materials that could blanket 100 square kilometers of American territory.[270]

Even as late as 1985, when Mikhail Gorbachev was blithely reassuring nervous Western interlocutors that he was resolutely reining in the remnants of the BWC-violating program, the illicit work on smallpox and other pathogens nonetheless continued apace.[271] Alibek

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267. *See* ALIBEK & HANDLEMAN, *supra* note 258, at 19, 110-15, 121-22 (asserting that a new aerosol form of a variola weapon was tested at Vector in December 1990, and the production line there was deemed capable of manufacturing 80-100 tons of smallpox virus annually); CTR. FOR CIVILIAN BIODEFENSE STUDIES, SMALLPOX (2002) (stating that "Russia still possesses an industrial facility that is capable of producing tons of smallpox virus annually and also maintains a research program that is thought to be seeking to produce more virulent and contagious strains"), http://www.hopkins-biodefense.org/pages/agents/agentsmallpox.html (last visited Apr. 5, 2003). See also an eight-part series of articles by William Kucewicz, *Beyond Yellow Rain: The Threat of Soviet Genetic Engineering*, WALL ST. J., April 23-May 18, 1984.

See also MONTEREY INST. OF INT'L STUDIES, *supra* note 261, at 9, 122-13 (noting that an accidental exposure during an open-air field testing of smallpox weaponry on Vozrozhdeniya Island in the Aral Sea in 1971 led to a small outbreak of the disease, with three deaths and nearly fifty thousand emergency vaccinations); William J. Broad & Judith Miller, *Traces of Terror: The Bioterror & Threat, Report Provides New Details of Soviet Smallpox Accident*, N.Y. TIMES, June 15, 2002, at A1; David Brown, *Soviets Had '71 Smallpox Outbreak*, WASH. POST, June 16, 2002, at A25; Judith Miller, *U.S. to Help Reduce Threat of Russian Arms*, N.Y. TIMES, Aug. 9, 2002, at A8.

268. ALIBEK & HANDELMAN, *supra* note 258, at 111-12.

269. Preston, *supra* note 144, at 46.

270. ALIBEK & HANDELMAN, *supra* note 258, at 6, 111-12, 140-41; *see also* Joby Warrick, *Russia's Poorly Guarded Past, Security Lacking at Facilities Used for Soviet Bioweapons Research*, WASH. POST, June 17, 2002, at A01 (noting that one standby facility, principally devoted to production of other BW agents, was capable of generating 200 tons per year of smallpox virus if war appeared imminent).

271. *See* ALIBEK & HANDELMAN, *supra* note 258, at 117-45; Tucker, *Biological Weapons in the Former Soviet Union*, *supra* note 265, at 1 (Alibek's work at Biopreparat, which included development of "three versions of a tularemia biological weapon, a sophisticated plague

claims that Gorbachev at that late date explicitly and personally approved at least the broad parameters of a $1 billion expansion in the bioweapons infrastructure, including funding a huge new Biopreparat viral reactor to enhance the processing of variola virus for manifestly offensive purposes.[272]

Today, it appears that the illegitimate offensive Russian BW work has at last been choked off, and a substantial effort, primed by at least a dollop of Western financial assistance, has succeeded in converting former weapons facilities and personnel into benign, civilian operations.[273] The flagship of Biopreparat, the Russian State Research Center of Virology and Biotechnology (Vector), has emerged as a leading institution on the forefront of many areas of peaceful biological and related research.[274] Smallpox, in particular, has been the subject of varied proposals for Western collaboration with the Vector laboratory, and the U.S. Departments of Defense and Health and Human Services have reviewed $5 million worth of proposed joint counter-bioterrorism projects focusing on development of refined capabilities for recognizing and diagnosing the illness and evaluation of candidate antiviral medications.[275]

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biological weapon, and a dry form of anthrax," continued through 1987); Orent, *supra* note 266 (alleging that an improved smallpox virus was tested on prisoners).

272. *See* ALIBEK & HANDELMAN, *supra* note 258, at 117-18 (asserting that Alibek had seen a document that Gorbachev had signed in 1985 authorizing a five-year $1 billion plan to develop new biological weapons, including an intensification of smallpox BW efforts). Advanced work to develop weaponized versions of Marburg, Ebola, Lassa fever, and other viruses continued at least until 1990. *Id.* at 133.

273. *See* James Clay Moltz, *Introduction: Assessing US Nonproliferation Assistance to the NIS*, NONPROLIFERATION REV., Spring 2000, at 55 (noting that since 1991 the United States has allocated $2.7 billion for nonproliferation assistance and weapons dismantlement activities in the former Soviet Union); Jonathan B. Tucker & Kathleen M. Vogel, *Preventing the Proliferation of Chemical and Biological Weapon Materials and Know-How*, NONPROLIFERATION REV., Spring 2000, at 88, 91 (noting Defense Department spending to secure Russian facilities); Jean Pascal Zanders & Maria Wahlberg, *Chemical and Biological Weapon Developments and Arms Control*, 2000 ARMAMENTS, DISARMAMENT & INTERNATIONAL SECURITY SIPRI Y.B. 509, 529-30; Judith Miller & William J. Broad, *Dollars Are Weapon of Choice in the War on Bacteria Peril*, N.Y. TIMES, Dec. 8, 1998, at A12; Warrick, *supra* note 270.

274. *See* Hoffman, *supra* note 264 (describing conversion from biological weapons into peaceful applications at the Biopreparat facility in Oblensk, Russia).

275. *See* TUCKER, *supra* note 95, at 227-28; Sergey V. Netesov, *The Scientific and Production Association Vector: The Current Situation, in* CONTROL OF DUAL-THREAT AGENTS: THE VACCINES FOR PEACE PROGRAMME, *supra* note 236, at 133, 133-38 (noting collaboration with the World Health Organization toward mapping the variola virus genome as well as other programs with international groups); Richard Stone, *Russia, NIH Float Big Plan for Former Soviet Bioweapons Lab*, 291 SCI. 2288, 2288 (2001) (discussing a proposal to transform Vector into the International Center for the Study of Emerging and Reemerging Diseases); Ken Alibek & Stephen Handelman, *Smallpox Could Still Be a Danger*, N.Y. TIMES, May 24, 1999, at A27 (asserting that four principal Soviet BW military installations remain off-limits for international inspectors).

At the same time, there is still a degree of secrecy associated with the facility, despite frequent American and other visitors and the injection of Western capital, technical advice, and collaboration.[276] Vector has, to date, refused to grant Americans full access to the smallpox research areas,[277] impeded efforts to maintain a U.S. scientist on-site to continuously monitor variola activities, and declined American requests for access to certain unique smallpox virus samples.[278] Accordingly, some observers continue to harbor doubts about the complete innocence of all Biopreparat's hidden corners.[279]

In addition, there are the twin dangers of inadequate physical security at some Russian facilities (with stocks of hazardous BW materials perhaps vulnerable to both petty theft and organized terrorist strikes)[280] and "brain drain" (with Russian scientists and military officials, extensively trained during the cold war in the arcane world of offensive variola BW, now bereft of remunerative and professionally rewarding opportunities in the post-Soviet economy, perhaps vulnerable to inducements to sell their expertise on the global black market to rogue states interested in perfecting a clandestine biological warfare capability of their own).[281]

F. BW Proliferation

The fear of the further spread of biological weapons capabilities, in fact, is one of the leading nightmares afflicting international security analysts today,[282] and the specter of smallpox is often at the fore-

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276. Peter Eisler, *U.S., Russia Tussle Over Deadly Anthrax Sample*, USA TODAY, Aug. 19, 2002, at 1A; *see also* Netesov, *supra* note 275, at 135-37 (stating that in 1990 Vector welcomed Western visitors with the objective of discussing joint ventures and research).

277. Eisler, *supra* note 276.

278. *Id.*

279. *See* Judith Miller, *CIA Hunts Iraq Tie to Soviet Smallpox*, N.Y. TIMES, Dec. 3, 2002, at A18 (noting Russia's possible biological weapons trade with Iraq); Orent, *supra* note 266 (expressing concern that covert BW work may still be proceeding in other Russian laboratories and that Russian BW experts may be tempted to offer their services to hostile employments); *see also* Eisler, *supra* note 276 (reporting that U.S. defense officials are attempting to acquire samples of specialized variants of anthrax and smallpox from Russian officials, but have been frustrated by Moscow's delays).

280. *See* Will Stewart, *Security Shambles As We Go Inside Smallpox Factory*, SUNDAY MIRROR, Dec. 8, 2002, at 23 (describing how one newspaper researcher was able to penetrate Vector security using false documents); Warrick, *supra* note 270 (detailing the marginal security improvements at Russian bioweapons facilities).

281. Scott Parrish & Tamara Robinson, *Efforts to Strengthen Export Controls and Combat Illicit Trafficking and Brain Drain*, NONPROLIFERATION REV., Spring 2000, at 112, 112. U.S. GEN. ACCOUNTING OFFICE, GAO/NSIAD-00-138, BIOLOGICAL WEAPONS: EFFORT TO REDUCE FORMER SOVIET THREAT OFFERS BENEFITS, POSES NEW RISKS 5, 10 (2000).

282. *See* Zanders & Wahlberg, *supra* note 273, at 526-28 (discussing international proliferation concerns and NATO's response).

front.[283] No fewer than ten countries have been the subject of recurrent public speculation as covert BWC violators.[284] In 2001, the United States publicly and formally accused five states—Iran, Iraq, Libya, North Korea, and Syria—of transgressing the Biological Weapons Convention, and stated that additional unnamed countries could be added to that unseemly indictment.[285]

The smallpox virus, in particular, has attracted the attention of these potential proliferators, and North Korea, Iran, and Iraq are repeatedly identified as leading suspects who may already have obtained secret variola inventories from Soviet/Russian or other sources.[286] Libya and Syria also frequently appear on the roster of participants in a "variola race";[287] others would add China, France, India, Israel, and perhaps Pakistan, Cuba, South Africa, and the Czech Republic as countries that may have covertly acquired the virus or attempted to do so.[288] The sparse evidence on the public record is far from conclusive

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283. *See* Lawrence K. Altman, *The Precautions; U.S. Sets Up Plan to Fight Smallpox in Case of Attack*, N.Y. TIMES, Nov. 4, 2001, at 1A (noting steps being taken by the Centers for Disease Control to prepare the country for a smallpox attack); Roxanne Roberts, *A War Game to Send Chills Down the Spine*, WASH. POST, Oct. 23, 2001, at C01 (reporting grim results of a military exercise simulating a release of smallpox by terrorists).

284. *See* ALIBEK & HANDELMAN, *supra* note 258, at 273 (explaining that Soviet intelligence did not know of any BW programs in Eastern European satellite states, but had detected evidence of such activities in Iraq, North Korea, China, Germany, and France); MILLER ET AL., *supra* note 203, at 98-123 (describing Iraqi BW program before and after the Gulf War); Zanders & Wahlberg, *supra* note 273, at 526-27; CENTRAL INTELLIGENCE AGENCY, UNCLASSIFIED REPORT TO CONGRESS ON THE ACQUISITION OF TECHNOLOGY RELATING TO WEAPONS OF MASS DESTRUCTION AND ADVANCED CONVENTIONAL MUNITIONS, 1 JANUARY THROUGH 30 JUNE 2001 (noting the suspected activity of Iran, Iraq, North Korea, Libya, Syria, Sudan, India, Pakistan, and Egypt), *at* http://www.cia.gov/cia/publications/bian/bian_jan_2002.htm (last visited Apr. 6, 2003).

285. Judith Miller, *Bioterror; U.S. Publicly Accusing 5 Countries of Violating Germ-Weapons Treaty*, N.Y. TIMES, Nov. 19, 2001, at B1 [hereinarter *Bioterror*]; Bolton, *supra* note 256, *at* http://www.state.gov/us/rm/janjuly/6231.htm. Later, the United States also formally accused Cuba of maintaining an illicit offensive BW program. Judith Miller, *Washington Accuses Cuba of Germ-Warfare Research*, N.Y. TIMES, May 7, 2002, at A6.

286. *See* Richard Preston, *The Specter of a New and Deadlier Smallpox*, N.Y. TIMES, Oct. 14, 2002, at A19.

287. *See* ALIBEK & HANDELMAN, *supra* note 258 (identifying Libya and Syria as two of the seventeen countries named by the U.S. Office of Technological assessment in 1995 as possessing biological weapons); CIRINCIONE, *supra* note 224, at 9 (listing Libya and Syria as two of "approximately twelve nations suspected of having biological warfare programs").

288. TUCKER, *supra* note 95, at 186, 205 (noting CIA and military intelligence conclusions that eight countries had retained undeclared variola stocks); William J. Broad & Judith Miller, *Government Report Says 3 Nations Hide Stocks of Smallpox*, N.Y. TIMES, June 13, 1999, § 1, at 1 (reporting that secret government intelligence assessment concluded that Iraq, North Korea, and Russia are probably concealing smallpox virus stocks); Brownlee, *supra* note 207 (speculating that the list may consist of Pakistan, Israel, South Africa, Libya, China, North Korea, and Iraq); Barton Gellman, *4 Nations Thought to Possess Smallpox*,

but is still very worrisome.[289]

Few would doubt any longer the potential havoc and suffering that deft application of smallpox or other biological weapons could inject into a battlefield. While earlier generations of CBW arms suffered categorically from imprecision, slowness, and other characteristics that impeded their military effectiveness, modern variants can be refined and steered with awesome effect.[290] Contemporary biological arms might be hardier, faster-acting, less susceptible to degradation through sunlight or rain, and more impervious to defenses than their predecessors.[291] Experts calculate that the cost per fatality of biological weapons such as smallpox would be much lower than the comparable figures for conventional, chemical, or even nuclear arms.[292] That potential lethality has not been lost on leading defense experts. Colin Powell, U.S. Secretary of State and former Chair of the Joint Chiefs of Staff, remarked after the Persian Gulf War, "Of all the various weapons of mass destruction, biological weapons are of the greatest concern to me."[293]

G. *Smallpox as a Terrorist Device*

Sub-national actors, too, have responded eagerly to the lure of CBW. Renegade use or attempted, threatened or hoax use of various

WASH. POST, Nov. 5, 2002 (reporting that the CIA now judges Iraq, North Korea, Russia, and France as possessing undeclared smallpox virus stocks).

289. North Korea and Iraq, for example, may have vaccinated their troops against smallpox, suggesting that they anticipate possible wartime exposure to the virus. *See* Broad & Miller, *supra* note 288 (stating that "blood samples from North Korean soldiers . . . show smallpox vaccinations" and that smallpox vaccine was being manufactured in Iraq).

290. *See* PILLER & YAMAMOTO, *supra* note 197, at 96-104 (explaining developments in biological weapons).

291. *See id.* at 22-25 (stating that "[t]he new biotechnologies promise to 'improve' CBW agents and enhance their ability far beyond the capacity of classical biochemistry, both qualitatively and quantitatively"); Carina Dennis, *The Bugs of War*, 411 NATURE 232 (2002) (discussing advances made in the production of smallpox); Richard Novick & Seth Shulman, *New Forms of Biological Warfare?*, *in* PREVENTING A BIOLOGICAL ARMS RACE, *supra* note 206, at 103, 113-16 (describing modifications made to biological agents that will improve their usefulness as weapons).

292. *See* LEONARD A. COLE, THE ELEVENTH PLAGUE: THE POLITICS OF BIOLOGICAL AND CHEMICAL WARFARE 8 (1997) (providing 1969 costs of various types of military operations, measured in casualties per square kilometer, ranging from $2000 for conventional arms, $800 for nuclear, $600 for chemical, and $1 for biological); Keay Davidson, *U.S. Gears Up for Smallpox Threat*, S.F. CHRON., Dec. 6, 2002, at A12 (quoting D.A. Henderson as estimating that for $200,000, several skilled workers could construct an "impressive smallpox arsenal" in a work space no larger than a two-car garage).

293. GRAHAM S. PEARSON, DELIBERATE DISEASE: WHY BIOLOGICAL WARFARE IS A REAL CONCERN 5 (Int'l Sec. Info. Serv., Briefing Paper No. 6, 1996).

poisons is of ancient provenance;[294] in recent years, however, as the relevant technology has come within reach of additional deviant individuals and groups, the practice has accelerated.[295] Both inside the United States and abroad, efforts to apply biological weapons—especially anthrax, but numerous other deadly agents, too—have become a distressingly familiar and expensive law enforcement and security problem.[296]

The events of September 11, 2001 mandate that we attend with new-found vigor to the danger that biological arms, smallpox prominent among them, might have an irresistible appeal for an array of these terrorist groups, perhaps even more than for regular armies.[297] Many have suggested that considerations of cost, accessibility, ease of delivery, and staggering effect upon the target population would combine to make modern BW the terrorists' "ultimate weapon."[298]

The bewildering anthrax attacks in October 2001[299] strongly reinforce this view. There, a group or individual, still unidentified as of this writing, mailed only a handful of contaminated letters to a few targets, resulting in five deaths and seventeen injuries.[300] But the social consequences and the disruptions occasioned by the inevitable accompanying blizzard of hoaxes, accidents, and cases of mistaken

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294. Jack Spencer & Michael Scardaville, *Understanding the Bioterrorist Threat: Facts and Figures*, HERITAGE FOUND. BACKGROUNDER, Oct. 11, 2001, at 2 (describing bioterrorist attacks dating as far back as 1346).

295. *See generally* TOXIC TERROR: ASSESSING TERRORIST USE OF CHEMICAL AND BIOLOGICAL WEAPONS (Jonathan B. Tucker ed., 2000) (presenting case studies of terrorist CBW attacks or attempted attacks in Germany, Chicago, Los Angeles, Tokyo and elsewhere).

296. *Id.* at 1-2; Spencer & Scardaville, *supra* note 294, at 1, 13-17.

297. Geissler, *supra* note 202, at 442.

298. *See* U.S. GEN. ACCOUNTING OFFICE, GAO/NSIAD-99-163, COMBATING TERRORISM: NEED FOR COMPREHENSIVE THREAT AND RISK ASSESSMENTS OF CHEMICAL AND BIOLOGICAL ATTACKS 2 (1999) (concluding that "terrorists would need a relatively high degree of sophistication to successfully cause mass casualties with some . . . chemical and most biological agents"); Jean Pascal Zanders et al., *Risk Assessment of Terrorism with Chemical and Biological Weapons*, 2000 ARMAMENTS, DISARMAMENT & INT'L SEC., SIPRI Y.B. 537, 537 (surmising that terrorists may cause mass casualties using "[r]elatively small amounts of chemical or biological (CB) warfare agents"); Bill Miller, *Study Urges Focus on Terrorism with High Fatalities, Cost*, WASH. POST, Apr. 29, 2002, at A03 (stating that a skillful terrorist biological attack could kill one million people and inflict $750 million in economic damage). *But see* Sheryl Gay Stolberg, *The Biological Threat; Some Experts Say U.S. Is Vulnerable to a Germ Attack*, N.Y. TIMES, Sept. 30, 2001, at A1 (reporting that carrying out a bioterrorist attack would be technically challenging).

299. Joby Warrick & Steve Fainaru, *Bioterrorism Preparations Lacking at Lowest Levels; Despite Warnings and Funds, Local Defenses Come Up Short*, WASH. POST, Oct. 22, 2001, at A7.

300. Toni Locy & Laura Parker, *Anthrax Case Remains Frustrating Mystery*, USA TODAY, Oct. 1, 2002, at 4A.

identification, were profound.[301] Senate and House office buildings in Washington, D.C. were closed for weeks;[302] many executive branch agency mailrooms were abruptly shuttered and reorganized;[303] major media headquarters in New York and elsewhere were disrupted;[304] and everyone across the country began to look with suspicion at even the slightest irregularity in incoming mail.[305] Even the President of the United States had to reassure a jittery public that he did not have anthrax,[306] and he continued to evade the question of whether he had received precautionary treatments of ciprofloxacin, the leading anti-anthrax medication, which was itself the subject of panic buying.[307]

A smallpox terrorism attack could be even worse.[308] Indeed, many experts would consider variola an "ideal" tool for deviant non-state actors.[309] The virus's lethality, the absence of any cure, and the fear and loathing it has always inspired in human beings combine to suggest that few BW agents could succeed in terrorizing a community as viciously as smallpox.[310] Moreover, unlike anthrax, smallpox is fully

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301. *See* Maria Glod, *Authorities Cracking Down as Terror Hoaxes Take Toll*, WASH. POST, Oct. 22, 2001, at A01 (providing examples of hoaxes and mistakes in Washington, D.C., Florida, Texas, Virginia, and Maine).

302. *See Washington in Brief*, WASH. POST, Jan. 17, 2002, at A04.

303. *See* Spencer S. Hsu, *Agency Responses to Mail Scares Vary; Lack of Uniformity Frustrates Some*, WASH. POST, Oct. 27, 2001, at A10.

304. *See* Locy & Parker, *supra* note 300.

305. *See* Glod, *supra* note 301 (reporting anthrax hoaxes and false alarms across the country).

306. Francis X. Clines, *U.S. Officials Voice New Worry After Traces of Anthrax Taint Off-Site White House Mailroom*, N.Y. TIMES, Oct. 24, 2001, at A1.

307. *See id.* (stating that "there was no word on whether [the President] had undergone the nasal swabbing or antibiotic treatment now familiar in the more intense anthrax precautions").

308. Lisa D. Rotz et al., *Public Health Assessment of Potential Biological Terrorism Agents*, 8 EMERGING INFECTIOUS DISEASES 225, 226 (2002) (explaining that a Centers for Disease Control panel rated variola as a top priority in the risk matrix).

309. Nicholas Wade, *Biological Warfare Fears May Impede Last Goal of Smallpox Eradicators*, 201 SCI. 329, 330 (1978) (alleging that despite the availability of a vaccine, "[s]mallpox is the ideal biological warfare agent since it is stable, easily aerosolized, simple to grow, and is a terrifying disease with high lethality"); David Brown, *Biological, Chemical Threat Is Termed Tricky, Complex; Smallpox Virus is Most Feared in Array of Deadly Weapons*, WASH. POST, Sept. 30, 2001, at A12 (claiming "[t]here's universal agreement that the smallpox virus is the single most dangerous raw material for a non-nuclear attack"); Mike Nartker, *U.S. Response: Bioterrorism Differs from Biowarfare, Official Says*, GLOBAL SEC. NEWSWIRE, Jan. 17, 2002 (quoting Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, as saying smallpox is "the perfect bioweapon" due to widespread population vulnerability and the absence of an adequate therapy), *available at* http://www.nti.org/d_newswire/issues/newswires/2002_1_17.html 7 (last visited Apr. 6, 2003).

310. *See* Marilyn Werber Serafini, *Ignorance Is No Defense*, 33 NAT'L J., 3094, 3094-96 (2001) (asserting that "[o]f all the infectious agents that terrorists might seek to use against the United States, the smallpox virus is perhaps the most feared, because it—unlike

communicable between people:[311] once an epidemic has been started, any person with vaguely flu-like symptoms becomes a potential disease agent and thus a subject of apprehension and even anger.[312] Ominously, Osama bin Laden has reportedly devoted resources to obtaining variola weaponry.[313]

In short, people should take only the slightest comfort in the fact that smallpox has not been used as a biological weapon or a terrorist device in the past half century. It is probably only the fact of limited access to variola that has provided that margin of safety. If rogue countries or rapacious terrorists could get their hands on the virus by extracting it from the two WHO inventories or in some other fashion, the combination of their seemingly unlimited hostility and variola's seemingly unlimited lethality could be tragic indeed.

III. GENETIC ENGINEERING AND "DESIGNER BUGS"

The third wonderful, yet ominous watershed event of 1973 was the initiation of genetic engineering.[314] Any description of the exquisite biotechnology underlying those DNA manipulation techniques surely lies well beyond the scope of this Article, but at least a brief introduction can provide a better basis for understanding the public policy choices and risks we now face.[315]

The first step in genetic engineering is identifying and isolating a particular gene—a segment of DNA or RNA that constitutes a unit of inherited information—in the originating or donor organism.[316] For

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anthrax, pneumonic plague and other potentially weapon-ready diseases—is highly contagious").

311. *Id.* at 3096.

312. On the other hand, there are also important reasons why terrorists might not consider smallpox to be an optimal tool, including the availability of an effective vaccine, the difficulty in obtaining access to variola virus samples, and the awkwardness of weaponizing variola in aerosol form. *See* U.S. CTRS. FOR DISEASE CONTROL, *supra* note 156, at 2 (noting that 90% of aerosolized smallpox dies within twenty-four hours); Siebert, *supra* note 140, at 55 (stating that most scientists think that smallpox would be a relatively poor biological weapon); HENDERSON, *supra* note 175 (noting the "special skills" required to grow and process smallpox), *at* http://www.hopkins-biodefense.org/pages/agents/risk.html.

313. *See* Gellman, *supra* note 288 (pointing out that although there is no evidence that al Qaeda has already obtained variola samples, the organization has spent money in an effort to acquire the virus).

314. *See* BERG & SINGER, *supra* note 13, at 5 (explaining that at a meeting in June 1973 scientists asked the National Academy of Sciences to study the risk of experimenting with recombinant DNA); Cohen, *supra* note 11, at 25 (noting that in 1973 scientists at Stanford University reported constructing "biological functional DNA molecules that combined genetic information from two different sources").

315. *See generally* BERG & SINGER, *supra* note 13, at 79-103 (describing the theory and background behind recombinant DNA methods).

316. *Id.* at 3.

example, human beings are thought to have upwards of 40,000 genes, while variola, relatively large and complex for a virus, has about 187.[317] A genetic map of a creature's entire gene sequence, or genome, can help locate the particular segments of greatest interest, and in the case of variola, scientists have now completed the full mapping for ten different strains of the virus.[318]

The specified gene is then deftly sliced out of the overall DNA structure, using specialized cutting enzymes, and the fragment is transferred into a target cell of another species.[319] This transportation can be accomplished in various ways. In one leading technique, a virus serves as the vector, and vaccinia virus (the close relative of variola used for anti-smallpox vaccinations) has proven to be a particularly adroit vehicle for this purpose.[320] The DNA snippet is woven into the virus's original genome, and the transformed virus is then allowed to perform its usual function—it invades the target cell and releases its now modified DNA into the host.[321] The routine process of viral infection involves the intruder's DNA insinuating itself into the host cell's original genome, so whenever the cell reproduces, it will generate additional identical copies of the altered genetic structure.[322] This "recombinant DNA" can thereby merge the genetic codes from two distinct creatures, permanently injecting a specified gene into the chromosomes of the target cell, which thereafter will evidence the altered behavior and pass the new trait along to succeeding cellular generations.[323]

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317. *See* Preston, *supra* note 144, at 54 (comparing the number of genes in smallpox DNA, 187, with that of the HIV virus, which has only 10).

318. Smallpox Eradication: Destruction of Variola Virus Stocks Report by the Secretariat, *supra* note 163, at 3.

319. BERG & SINGER, *supra* note 13, at 99-102.

320. *See* Bernard Moss, *Vaccinia Virus: A Tool for Research and Vaccine Development*, 252 SCI. 1662, 1664-65 (1991) (explaining that vaccinia is much more efficient than most alternative methods for inserting genetic material into a target cell).

321. Theodore Friedmann, *Overcoming the Obstacles to Gene Therapy*, SCI. AM., June 1997, at 96, 98; Philip L. Felgner, *Nonviral Strategies for Gene Therapy*, 276 SCI. AM., June 1997, at 102, 102.

322. *See* FENNER ET AL., *supra* note 14, at 71 (noting that variola is unusual because it replicates itself in the cytoplasm of the invaded cell, while most other viruses invade the cell's nucleus to accomplish their functions).

323. *See* BERG & SINGER, *supra* note 13, at 227 (noting that recombinant DNA technology, through "introduction of altered genes into cells and whole organisms" enables biologists to better understand normal and abnormal physiological states and therefore is among the most "profound implications" of genetic engineering).

A. "*Pharm Animals*"

Amazing juxtapositions can be created in this way, marrying the genetic legacies of organisms that could never mate in nature.[324] Bacteria, for example, are relatively easy to manipulate.[325] Scientists can now shanghai the genetic code of E. coli and related creatures, transforming them into entities that can gobble oil spills,[326] fix nitrogen,[327] or produce human growth hormone[328] (to treat dwarfism) and insulin[329] (to deal with diabetes). Likewise, larger animals—goats and pigs, for example—can be converted into factories that will generate rare human "protein C," to assist in blood clotting.[330]

Comparable courses of gene therapy can also engineer previously unimaginable plants that secrete their own insecticides,[331] orchards that produce larger or more nutritious fruit,[332] trees that grow taller and straighter with less water and fertilizer,[333] and "pharm animals"[334] that promise greater livestock hardiness, variety, and economy. Transgenic mammals may also be crafted with key aspects of the human immune system, to serve as a reliable source of organs to transplant into sick or injured humans, with less danger of rejection.[335] Likewise, genetically modified mice or even primates can serve as models

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324. *See* Cohen, *supra* note 11, at 25 (describing genetic engineering as a means of overcoming the "natural barriers that normally prevent the exchange of genetic information between unrelated organisms").

325. *See id.* at 25 (discussing the manipulation of E. coli).

326. *See* Bryn Nelson, *The DNA Revolution: A Once-Overlooked Molecule Unlocked Life's Secrets and Changed Science Forever*, N.Y. NEWSDAY, Jan. 26, 2003, at A6 (noting that General Electric in 1980 received the first patent for bacterium engineered to assist in cleaning up oil spills).

327. *Biotechnology Has Come a Long Way*, MALAYSIAN BUS., Dec. 1, 2001 (noting that genetically modified bacteria that assist plants to fix nitrogen may save farmers money on nitrogen fertilizers).

328. *Argentina Cow Clone Step Toward More Plentiful and Cheaper Growth Drug; Human Growth Hormone*, TRANSPLANT NEWS, Aug, 26, 2002.

329. Martinelli, *supra* note 13, at 243, 247.

330. William H. Velander et al., *Transgenic Livestock as Drug Factories*, SCI. AM., Jan. 1997, at 70, 70.

331. BERG & SINGER, *supra* note 13, at 239.

332. *Id.*

333. Marc Kaufman, *Tweaking Genes to Help Plants Survive Elements*, WASH. POST, Oct. 21, 2002, at A09.

334. *See* Carol Kaesuk Yoon, *If It Walks and Moos Like a Cow, It's a Pharmaceutical Factory*, N.Y. TIMES, May 1, 2000, at A20 (describing "pharm animals" as creatures "concocted by plucking a gene from one organism and inserting it into the DNA of another").

335. *Raising Pigs for Organ Transplant*, AGJOURNAL, Mar. 14, 2000, http://www.agjournal.com/story.cfm?story_id=737 (last visited Mar. 15, 2003) (stating that researchers have produced cloned pigs through a method that may lead to future successful pig organ transplants into human beings).

for testing new medicines, including novel anti-smallpox preparations, before human trials could be safely undertaken.[336]

B. *Military Applications*

There is, however, a dark side to this new technology.[337] History suggests that scientific advances—airplanes, radios, computers, and all the rest—have sooner or later (and usually sooner) been turned to military applications, as well as to their various peaceful civilian uses.[338] Biotechnology can be no different in this regard, and the potential employments in biological warfare are truly intimidating.[339] Just as the vaccinia virus has already proven to be a remarkably adaptable substrate for genetic engineering, perhaps other members of the orthopoxvirus genus, variola in particular, could be manipulated with equal power, but this time to magnify the pathogenic possibilities.[340] The prospect of "designer bugs,"[341] potential BW agents possessing a witch's brew of enhanced characteristics, is not beyond the imagination and may already be within reach.[342]

BW agents modified by specialized genetic hitchhikers might be crafted to display all manner of invidious traits: greater lethality; quicker communicability; resistance to existing vaccines; and greater persistence in soil, air, and water (or if the attacker's strategy so demanded, a much shorter lifespan, to enable an invading force to oc-

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336. *See, e.g.*, Erika Check, *Monkey Smallpox Trial Suspended Over Painkiller Use*, 418 NATURE 265, 265 (2002) (reporting interruption of U.S. Army's testing of smallpox illness in primates because of concerns over their pain).

337. In fact, there may be multiple potential down sides to genetic engineering: many consumers remain dubious about the safety of genetically modified foodstuffs; at least one experiment in gene therapy resulted in the death of the patient, leading to suspension of related work at the University of Pennsylvania; the rapaciousness of the efforts to secure patent protection for the results of genetic engineering has troubled intellectual property law; and there are worries that genetic profiling may lead to disadvantages for people with unfavorable genetic markers. *See* Kathryn Brown, *Seeds of Concern*, SCI. AM., Apr. 2001, at 52, 52; Eliot Marshall, *Gene Therapy on Trial*, 288 SCI. 951 (2000); Andrew Pollack, *Scientists Ponder Limits on Access to Germ Research*, N.Y. TIMES, Nov. 27, 2001, at F1; Robert P. Lanza et al., *Xenotransplantation*, SCI. AM., July 1997, at 54, 59.

338. Matthew Meselson, *Averting the Hostile Exploitation of Biotechnology*, 48 CBW CONVENTIONS BULL., June 2000, at 16, 16.

339. *Id.* at 16.

340. Preston, *supra* note 286 (noting that pox viruses are among the easiest to genetically modify because they so readily accept foreign genes, and that new strains of variola could probably be genetically engineered in a small facility in relative safety, with little prospect of outside detection).

341. Jon Cohen, *Designer Bugs*, ATLANTIC MONTHLY, July/August 2002, http://www.theatlantic.com/issues/2002/07/cohen-J.htm (last visited May 20, 2003).

342. *See* Dennis, *supra* note 291, at 232 (discussing recent advances by researchers "mixing and matching traits from different microorganisms").

cupy the battlefield that much sooner).[343] They might insinuate themselves in unusual, unforeseen ways to circumvent existing defenses. Perhaps they could be masked as natural outbreaks of disease, so the victimized nation would not even recognize that it had been deliberately attacked, or by whom.[344] Conceivably, a recombinant BW agent could be made "ethnically selective," in targeting only those populations possessing certain racially unique attributes, while leaving the attacker's home civilization intact.[345]

This specter is not simply a future fantasy: the U.S.S.R. may already have done it. The defector Ken Alibek asserted that Biopreparat had succeeded in crafting a horrific "chimera" BW agent—one that combines into a single pathogen the most evil features of two or more distinct biological weapons agents, such as variola, Ebola, or Venezuelan equine encephalitis.[346] U.S. critics contest whether such biological cocktails were actually created and whether they would necessarily be more dangerous than a simple low-technology alternative of merely inserting both types of virus into a single warhead or bomb.[347] But there is no doubt that this type of deft, malevolent bioengineering may already be feasible, and that variola may be an especially attractive vehicle for it, based upon its large size and manipulability, as well as its unusual "transfection" ability to revive seemingly dead virus particles via exposure to living relatives.[348]

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343. PILLER & YAMAMOTO, *supra* note 197, at 22-24, 96-104.

344. *Id.* at 23.

345. Malcom Dando, *Benefits and Threats of Developments in Biotechnology and Genetic Engineering*, 1999 ARMAMENTS, DISARMAMENT & INT'L SEC., SIPRI Y.B. 596, 598, 609 (suggesting that an ethnically-sensitive BW weapon might be feasible as the Human Genome Project provides additional detailed information regarding the sequence and function of the full DNA chain); *see also* PILLER & YAMAMOTO, *supra* note 197, at 24, 99-100; Erhard Geissler, *New Assessments of the Potential Value of BW and TW Agents, in* STRENGTHENING THE BIOLOGICAL WEAPONS CONVENTION BY CONFIDENCE-BUILDING MEASURES, *supra* note 227, at 15, 17 (Erhard Geissler ed., 1990) (discussing the possibility that CBW agents could be made ethnically sensitive); Dennis, *supra* note 291, at 233.

346. ALIBEK & HANDELMAN, *supra* note 258, at 259-61.

347. Davidson, *supra* note 292 (discussing D.A. Henderson's conclusion that it would be difficult to genetically engineer a stronger strain of variola, and his doubts that Soviet scientists had succeeded in doing so); Geissler, *supra* note 202, at 428 (suggesting that natural pathogens are so deadly that military forces or terrorists would have no need to resort to genetic engineering to improve upon them); *see also* ALIBEK & HANDELMAN, *supra* note 258, at 258-62; TUCKER, *supra* note 95, at 157-59; Andrew Pollack, *With Biotechnology, a Potential to Harm*, N.Y. TIMES, Nov. 27, 2001, at F6 (describing critics' doubts that the Soviet Union had produced such weapons).

348. FENNER ET AL., *supra* note 14, at 80 (stating transfection occurs when a target cell is simultaneously infected with both a dead, but physically intact, variola virus, and a live copy of some other member of the Chordopoxvirinae subfamily; the enzymes from the latter can help reconstitute and unleash the former, and fully communicable smallpox is produced).

The dual capability phenomenon plays a role here, too, as does the traditional scientific ethos of openness in publishing research results.[349] That is, explorations into the variola genome—necessary to develop better vaccines and antidotes—may simultaneously reveal opportunities for circumventing those same evolving safeguards.[350] There is something of a race between those who would craft improved defenses against traditional or emerging diseases versus those who would seek to multiply the pathogenic possibilities, and there is no guarantee that the peaceful side of the ledger will always advance faster.[351]

One specific illustration of the danger: as researchers unwrap the genetic mysteries of variola, they have undertaken to publish their results[352] for other scientists to review and to build upon. The full genomes for several strains of variola have already been displayed on the Internet, and others will follow.[353] This generosity promotes free exchange of ideas and, not incidentally, helps reassure apprehensive observers that the initial researchers are not seeking any one-sided military advantage in smallpox BW.[354] But it also makes the fruits of those labors readily available to those who would exploit them for weapons purposes. It enables malicious DNA manipulators to save some steps in trying to figure out how to twist the variola chromosome in an even more despicable direction.[355]

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349. *See* Peter Aldhous, *Biologists Urged to Address Risk of Data Aiding Bioweapon Design*, 414 NATURE 237, 237-38 (2001) (discussing possibility of malign applications of published data from legitimate projects).

350. *See id.* (expressing concern "about projects in which viruses are engineered to evade or manipulate the immune system").

351. MILLER ET AL., *supra* note 203, at 64 (quoting U.S. bioweapons designer Bill Patrick, "[i]t takes eighteen months to develop a weapons-grade agent and ten years to develop a good vaccine against it"); Geissler, *supra* note 345, at 18-19 (discussing military specifications for use of BW and CW effectively in warfare); Douglas J. Feith, *Biological Weapons and the Limits of Arms Control*, NAT'L INT., Winter 1986-87, at 80, 81 (asserting that BW competition systematically favors offenses over defenses, because "[n]ew agents can be produced in hours; antidotes may take years").

352. *See, e.g.*, POXVIRUS BIOINFORMATICS RESOURCE CTR., COMPLETE GENOMES AVAILABLE IN THE POXVIRUS BIOINFORMATICS RESOURCE (listing two strains of variola major, and one of variola minor, as well as three substantial fragments, for which the full DNA encoding is publicly available), *at* http://www.poxvirus.org/viruses.asp (visited Apr. 7, 2003).

353. *See id.*

354. *See* Aldhouse, *supra* note 349, 237-38 (discussing pros and cons of publishing potentially dangerous research results).

355. *See* Jennifer Couzin, *A Call for Restraint on Biological Data*, 297 SCI. 749 (2002) (detailing members of Congress' criticism of publishing unclassified scientific data that could be of use to terrorists); Abigail Salyers, *Science, Censorship, and Public Health*, 296 SCI. 617, 617 (2002) (arguing against any attempt to restrict scientific publication as part of the effort to impede bioterrorism); Rick Weiss, *Polio-Causing Virus Created in N.Y. Lab*, WASH. POST, July 12, 2002, at A01 (noting that scientists can now create a viable polio virus by

C. *Variola Research Today*

Until quite recently, relatively little variola-focused scientific research had been undertaken in the United States. There were occasional proposals to initiate a new program, but for the most part, considerations of cost and competing priorities left the long-dormant CDC samples largely undisturbed.[356] In 1998-99, however, fresh impetus emerged when the U.S. Departments of Defense, Energy, and Health and Human Services jointly tasked the Institute of Medicine (IOM), a branch of the National Academy of Sciences, to advise them on the future scientific needs for retaining live variola virus for research purposes.[357] Subsequently, when the WHO in 1999 acquiesced once again in deferring the planned destruction of the virus, it did so with the understanding that a limited range of discrete research objectives of the sort outlined by IOM would be pursued.[358] Only a small window of time was to be allotted for these purposes, and the WHO specified that the inquiries must be conducted openly and would be carefully monitored by the organization's own experts.[359]

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following the published genome information, and perhaps could soon accomplish the same feat with variola); *see also* Raymond A. Zilinskas & Jonathan B. Tucker, *Limiting the Contribution of the Open Scientific Literature to the Biological Weapons Threat*, J. HOMELAND SECURITY, Dec. 2002, *at* http://www.homelandsecurity.org/journal/Articles/tucker.html (last visited Apr. 7, 2003) (discussing the problems posed by publication of variola research results).

Other commentators minimize the danger of misuse of such technical information, noting that there are much easier ways for terrorists to obtain suitable BW capabilities and that genetic engineering of variola DNA would be a most unlikely avenue for them to pursue, even if assisted by the published genomic data. *See* Nicholas Wade, *DNA Map for Bacterium of Plague Is Decoded*, WASH. POST, Oct. 4, 2001, at A13 (noting that biologists have decoded the full genetic map of the plague bacterium, another development that could be used both for medical and hostile purposes).

356. HENDERSON, *supra* note 175 (stating that very few U.S. research projects had been undertaken with intact variola in the prior twenty years), *at* http://www.hopkins-biodefense.org/pages/agents/risk.html. In 1995, the U.S. Departments of Defense and Health and Human Services had commissioned a joint report on variola research possibilities, which recommended a short-term program in pursuit of enhanced antiviral medications, new vaccines, and improved animal models for validating derived medicines. However, only a portion of the recommended research was actually conducted. INST. OF MED., *supra* note 170, at 11, 39-41. *See also* HENDERSON, *supra* note 158 (describing the internal politics leading to the 1995 decisions, and the research activity generated thereafter, for which funding was limited and progress was slow), *at* http://www.hopkins-biodefense.org/pages/news/deliberations.html.

357. INST. OF MED., *supra* note 170, at vii; *see* TUCKER, *supra* note 95, at 198 (stating that government agencies sought a technical assessment of future research activities that might require access to live, intact variola samples).

358. World Health Assembly, Res. 52.10, *supra* note 165, at 1-2.

359. *Id.* Of course, the projected December 31, 2002 deadline for completion of that contemplated research has now slipped, too. *See generally* Advisory Comm. on Immuniza-

The IOM report identified several different types of research that could usefully be undertaken before the final destruction of the variola samples. Foremost among the goals would be the development of an efficacious antiviral medication for employment in the event of a future outbreak of smallpox or of other related viral diseases.[360] Currently, there is no worthwhile prescription to combat variola;[361] one or two compounds have demonstrated some possible utility, but much more work needs to be done, including rigorous testing of candidate medications against live variola samples, both in vitro and in animals.[362]

A second objective would be the articulation of an improved vaccine—a prophylactic treatment that would safeguard against variola without carrying so many of the dangers and contraindications that have troubled the vaccine since Jenner's era.[363] Some have suggested that vaccinia, if it were to be proffered for the first time as a new drug today, would not win approval from the U.S. Food and Drug Administration (FDA), for failing to meet modern standards for safety and purity, and because it carries far more adverse side effects than any other vaccination currently on the market to combat any other disease.[364]

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tion Practices, *Vaccinia (Smallpox) Vaccine Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, MORBIDITY & MORTALITY WKLY. REP. , June 22, 2001, at 1.

360. Public health officials have become worried about an upsurge in human monkeypox—a deadly but previously rare disease that has in recent years become much more common in Central Africa and much more successful at being transmitted between human hosts. The monkeypox virus belongs to the same genus as variola and vaccinia, and the traditional anti-smallpox vaccination would provide protection against monkeypox, too, but in a region where so many people have been afflicted with HIV, and are therefore poor risks for vaccinia treatments, an improved vaccine or antiviral would be very valuable. *See* Joel Breman & D.A. Henderson, *Poxvirus Dilemmas—Monkeypox, Smallpox, and Biologic Terrorism*, 339 NEW ENG. J. MED. 556, 556 (1998); Jon Cohen, *Is An Old Virus Up to New Tricks?*, 277 SCI. 312 (1997); Wendy Orent, *Killer Pox in the Congo*, DISCOVER, Oct. 1, 1999, at 74; WORLD HEALTH ORG., MONKEYPOX, FACT SHEET NO. 161 (1997), *available at* http://www.who.int/inf-fs/en/fact161.html (last visited Apr. 7, 2003).

361. INST. OF MED., *supra* note 170, at 47.

362. *Id.* at 47-49. *But see* D.A. Henderson & Frank Fenner, *Recent Events and Observations Pertaining to Smallpox Virus Destruction in 2002*, 33 CLINICAL INFECTIOUS DISEASES 1057, 1057-59 (2001) (questioning the feasibility and wisdom of pursuing new antiviral drugs for smallpox).

363. INST. OF MED., *supra* note 170, at 53-58 (addressing the development of new vaccines and the obstacles encountered in the search for a vaccine for immunocompromised patients).

364. *Id.* at 55; *see also* Advisory Comm. on Immunization Practices, *supra* note 359, at 12-13 (describing complications associated with the smallpox vaccine); Moss, *supra* note 320, at 1664-65 (stating that the traditional vaccinia serum "was not sterile and undoubtedly would not meet modern standards of purity and safety were it introduced today").

Only slightly lower on the IOM priority list were two kinds of long-sought improvements in the power to detect and identify variola with accuracy and speed.[365] First, more rapid diagnostic tests and procedures would be desirable in order to be able to confirm a case of smallpox in the human body earlier and easier.[366] Second, military officials covet an ability to sense the virus in the environment, as in an oncoming aerosol cloud of possible biological weaponry released by a hostile enemy on the battlefield or by terrorists in an urban locale.[367]

Some of these objectives, and other functions that the IOM also identified,[368] would require sustained access to complete, viable variola virus, but for others, the critical experiments might be able to proceed by using only non-infective fragments.[369] Nevertheless, even the expertise of the leading virologists and immunologists of the IOM could not predict with certainty just when and how success in the research program will ultimately be achieved.

Moreover, the danger of untoward—possibly even disastrous—events cannot be entirely excluded. Accidents do happen, even when people and institutions are being honest and careful. And surprising results sometimes take a research program into unforeseen and unwanted directions. In 2001, for example, it was announced that a team of Australian researchers had been seeking a new method for controlling rodent populations by genetically altering the existing

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The leading smallpox vaccination used in the United States, known as Dryvax, was first officially licensed by the Food and Drug Administration in the 1970s, but that authorization lapsed, and the manufacturer also needed fresh approval for the bifurcated needles used to administer it and for the diluents (the liquids used to reconstitute freeze-dried vaccine). *See* Ceci Connolly, *FDA Grants License for Smallpox Vaccine*, WASH. POST, Nov. 2, 2002, at A13. That new license was granted only in October, 2002. *See id.* Other smallpox vaccines, including those donated by Aventis Pasteur and the additional millions being produced by Acambis, PLC and Baxter International, Inc., will still require a lengthy certification process. *Id.* Until that FDA review is completed, those vaccines could be administered only under protocols applicable to investigational new drugs, which require a cumbersome process of informed consent by each patient and careful post-vaccination monitoring. *Id.*

365. INST. OF MED., *supra* note 170, at 59.

366. *Id.* at 61-62.

367. *See id.* at 60-61.

368. Other objectives highlighted by the Institute of Medicine panel included refined mapping of the variola genome, enhanced understanding of the biological processes of infection, and uncovering additional details regarding the cellular operations of the virus. *Id.* at 63-71.

369. *See id.* at 84-85 (summarizing the committee's analysis of which research objectives depend upon access to live variola, and which could proceed with less dangerous substances).

mousepox virus to craft a contagious contraceptive.[370] They stumbled instead upon a technique for transforming that usually mild virus into a deadly killer—a strategy that might also be adapted for the creation of a "super" variola strain, immune to traditional vaccination. This event serves as a timely warning that our current prowess in the field of genetic engineering can veer without advance notice into intensely hazardous outcomes.[371]

D. *Costs of the Research*

These research programs, of course, are not free. One measure of the cost is the exploitation of the scarce facilities in which these ultra-hazardous experiments can proceed and the devotion of the few scientists capable of conducting such sophisticated virology inquiries.[372] Because of the manifest dangers, work on intact variola can be undertaken only within the confines of the most stringently-controlled installations. These laboratories must be certified as meeting the standards of "bio-safety level 4" (BL-4), incorporating multiple, redundant separations between pathogens and people.[373] These facilities are unusual: there are only two in the United States (at the CDC in Atlanta, and at the Army's Fort Detrick in Frederick, Maryland), and perhaps four more around the world.[374] Smallpox experiments, therefore,

370. *See* William J. Broad, *Australians Create a Deadly Mouse Virus*, N.Y. TIMES, Jan. 23, 2001, at A6 (reporting the discovery made by scientists at the Australian National University in Canberra); Cohen, *supra* note 341, http://www.theatlantic.com/issues/2002/07/cohen-j.htm. The mousepox virus is yet another member of the remarkably diverse orthopox virus genus that includes variola.

371. *See* Broad, *supra* note 370 (stating that the discovery was made in 1999, but it was not reported until 2001); *see also* Dennis, *supra* note 291, at 232; Gerald Epstein, *Controlling Biological Warfare Threats: Resolving Potential Tensions Among the Research Community, Industry, and the National Security Community*, 27 CRITICAL REVIEWS IN MICROBIOLOGY 321, 335 (2001) (noting that "if the human immune system responded to smallpox virus in the same way that the mouse responded to the related mousepox, adding [a particular modified gene] could increase smallpox's 30% fatality rate to 100%"); Ronald J. Jackson et al., *Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox*, 75 J. VIROLOGY 1205, 1208-09 (2001) (explaining that a certain modified gene, when added to a virus related to mousepox, can be lethal).

372. *See* INST. OF MED., *supra* note 170, at 39 (explaining how research on variola is difficult because of the lack of facilities equipped to hold the virus).

373. *See id.* at 37 (noting that BL-4 requires "a separate building or clearly isolated section of a building with a sealed internal shell[;] [o]uter and inner change rooms separated by a shower[;] . . . [a] double-doored autoclave[;] . . . [s]ewer and ventilation lines" equipped with special filters; individual supply and exhaust air tubes; and air pressure differentials to ensure that air will flow inward to the more tightly-constrained environments).

374. *See* Martin Enserink, *The Boom in Biosafety Labs*, 288 SCI. 1320, 1320-21 (2000) (listing known and proposed BL-4 labs); Laurie Garrett, *The Return of Infectious Disease*, FOREIGN AFF., Jan./Feb. 1996, at 66, 76 (explaining that of the existing BL-4 laboratories, "[l]ocal

must compete for time and attention with all other research into other highly dangerous pathogens, which likewise can be conducted only ensconced in BL-4 protections.[375] Some have argued, therefore, that it is a mistake to place such a high priority on further smallpox investigations when doing so inevitably displaces some inquiries into AIDS, Ebola, West Nile, or other viral or bacterial agents of even greater contemporary concern.[376]

Similarly, the projected fiscal costs of a smallpox research program are intimidating. The typical timeline for introducing a new pharmaceutical is extended and pricey: some say it can take ten to twenty years and $500 million to research, develop, test, and certify a new medication.[377] Would private enterprise be willing to invest in such an extended campaign when the payoff—an anti-smallpox medicine that may never be needed or purchased—is so contingent? The World Health Organization certainly has no budgeted funds to subsidize such an undertaking. Is it likely that the U.S. government would devote adequate money over such a long term to deal with a "dead" disease?[378]

Moreover, the ordinary developmental sequence is even more problematic here, since traditional human trials could not ethically be conducted with an illness as dangerous and incurable as smallpox.[379] The FDA, therefore, must modify its usual procedures for evaluating

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political instability threatens to compromise the security of the two labs in Russia, and budget cuts [may jeopardize] . . . the two in the United States and the one in Britain").

375. *See* INST. OF MED., *supra* note 170, at 39 (noting that live variola viruses have not recently been researched as thoroughly as more immediately threatening viruses).

376. *See* Siebert, *supra* note 140, at 44 (noting some other dangerous viruses also stored in BL-4 facilities).

377. WORLD HEALTH ORG., OVERCOMING ANTIMICROBIAL RESISTANCE: WORLD HEALTH REPORT ON INFECTIOUS DISEASES 2000, *at* http://www.who.int/infectious-disease-report/2000/other_versions/index-rpt2000_text.html (last visited Apr. 21, 2003); *see also* Preston, *supra* note 144, at 56 (quoting D.A. Henderson as predicting that "to get a new antiviral drug against smallpox is going to cost three hundred million dollars. The money simply isn't there.").

378. Shannon Brownlee, *Bad Reaction*, NEW REPUBLIC, Oct. 28, 2002, at 15 (explaining that pharmaceutical companies will not rush to produce anti-terrorism drugs when the only likely market is driven by the federal government instead of by consumers); Rino Rappuoli et al., *The Intangible Value of Vaccination*, 297 SCI. 937, 937-39 (2002) (noting that the commercial market does not reflect the full social value of vaccines, so governments ought to act to make the market more attractive to industry); Marilyn Werber Serafini, *Lieberman Pushes for More Bioterrorism Cures*, 34 NAT'L J. 2003 (2002) (describing legislative proposals to offer tax incentives, enhanced patent protection, and liability indemnification to induce pharmaceutical companies to invest more resources in research into antidotes against bioterrorism threats).

379. Kathryn C. Zoon, *Vaccines, Pharmaceutical Products, and Bioterriorism: Challenges for the U.S. Food and Drug Administration*, 5 EMERGING INFECTIOUS DISEASES 534, 534-35 (1999).

and approving candidate new medications. The agency has already indicated a sensible willingness to proceed with unusual dispatch and flexibility regarding assessment of the efficacy of variola medications entirely through animal trials, but a thorough program has yet to be implemented.[380]

In short, genetic engineering capabilities have flowered in the past three decades and now surge beyond earlier predictions, beyond the recognition of the general public, and perhaps beyond social control. We now possess an unparalleled ability to manipulate the genomes of variola and all manner of other creatures—for good or for ill.

IV. CURRENT STATUS

How do we now pull together the three strands—smallpox disease eradication, BW arms control, and genetic engineering—that serendipitously emerged together in modern form beginning in 1973? This section updates the relevant stories, focusing on their shifting interactions, assessing our current situation in each area, and summarizing the public policy dilemmas that their inexorable combination now poses.

A. *Smallpox*

The crucible of September 11, 2001 has prompted a great many changes in U.S. government policy and global practice,[381] two of which are of special importance for the struggle against smallpox. First, the Bush administration hardened the United States opposition to the imminent destruction of the last known remaining variola samples, thus completing a remarkable *volte face* in the American pos-

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380. *Id.*; *see also* New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible, 67 Fed. Reg. 37,988 (May 31, 2002) (to be codified at 21 C.F.R. pts. 314 and 601); INST. OF MED., *supra* note 170, at 50-51 (stressing the importance of developing adequate animal models for studying smallpox, since candidate medications cannot be tested in human subjects); Check, *supra* note 336, at 265 (noting that difficulties have emerged regarding FDA certification of U.S. Army's experimental treatments of smallpox in animal models, due to concern for the animals); D.A. Henderson & Frank Fenner, *Recent Events and Observations Pertaining to Smallpox Virus Destruction in 2002*, 33 CLINICAL INFECTIOUS DISEASES 1057, 1058 (2001) (observing that testing the variola virus on humans would not be possible unless there was an epidemic); Marilyn Werber Serafini, *A New Smallpox Vaccine: How Safe?*, 33 NAT'L J. 3371 (2001); Altman et al., *supra* note 15; Mark Kaufman, *FDA Acts to Speed Bioterror Medicines*, WASH. POST, May 31, 2002, at A01.

381. *See* Miller, *Bioterror*, *supra* note 285, (discussing how "[a] new awareness of the dangers of germ weapons began with the Sept. 11 attacks").

ture.[382] Starting in 1985, the U.S. delegation to the WHO annual meetings had consistently championed eradication. Louis W. Sullivan, then Secretary of Health and Human Services, announced at an international health meeting that "there is no scientific reason not to destroy the remaining stocks of the wild virus,"[383] and he promised to wipe out the CDC variola inventory promptly.[384] That position had been affirmed as recently as 1996, with the U.S. representative advising the WHO that "a two-year scientific and policy review in her country had concluded in favour of destroying the variola virus" and she "hoped that the international community would commit itself firmly to the chosen date."[385]

By 1999, the Clinton administration reluctantly tacked in the other direction, promoting a delay in destruction, and successfully urging the WHO to allow two to three additional years of research of the sort that the IOM had identified as being particularly worthwhile in combating the threat of a re-emergence of smallpox.[386] In late 2001, however, as that supposedly final extension of variola's suspended animation was proceeding, the Bush administration significantly raised the bar.[387] In the era of dramatically heightened anti-terrorism concerns, five new criteria would have to be satisfied before the viral samples could be eliminated, including development of: (1) a new vaccine, unencumbered by the side effects of vaccinia; (2) two new antiviral pharmaceuticals, which would combat smallpox through two independent cellular mechanisms; (3) enhanced environmental detectors to identify variola quickly in the event of wartime or terrorist applications; (4) augmented diagnostic capabilities for prompt confirmation of individual smallpox infections; and (5) a new capacity for combating even genetically-altered modifications of the virus.[388]

Acknowledging the radically altered security environment, the Director General of the WHO quickly acquiesced to this new strategy in

382. Judith Miller, *Germ Warfare; U.S. Set to Retain Smallpox Stocks*, N.Y. TIMES, Nov. 16, 2001, at A1.

383. Siebert, *supra* note 140, at 33.

384. *Id.*

385. World Health Org., Committee A, Provisional Summary Record of the Seventh Meeting, at 3, A49/A/SR/7 (1996); *see also* TUCKER, *supra* note 95, at 178-89 (noting the positions of various countries with regard to the destruction of the variola virus stocks and tracing the period of time over which these decisions were made).

386. *Smallpox Eradication: Destruction of Variola Virus Stocks, Report by the Secretariat*, *supra* note 165, at 1.

387. David Brown, *U.S. Wants the Smallpox Virus Preserved for Further Research*, WASH. POST, Nov. 17, 2001, at A9.

388. Miller, *supra* note 382.

December 2001;[389] the organization's executive board concurred in January 2002;[390] and the assembly (the top policy-making body in the WHO) swallowed the new approach in May 2002.[391]

The second important policy shift occasioned in autumn 2001 was the sudden American decision to procure massive amounts of smallpox vaccine immediately and to consider making it available to the general U.S. population.[392] Again, this u-turn in strategy had older roots: The United States had terminated the routine smallpox vaccination of civilians in 1972,[393] and halted the practice for military personnel after 1990, after concluding that the low risk of exposure to the disease did not justify the continuous cost of sometimes fatal side effects.[394] In the years following the WHO's glorious global triumph over the disease, the U.S. commitment to maintain a standby stockpile of vaccine had atrophied. All vaccine production was halted in the mid 1970s,[395] and by 2000, it was estimated that only six to fifteen million doses of vaccine remained in the United States, and much of it had suffered discoloration and other effects of aging that caused some to question its continuing potency.[396]

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389. *See Smallpox Eradication: Destruction of Variola Virus Stocks, Report by the Secretariat*, *supra* note 165, at 1.

390. World Health Org., *Statement by the Director-General to the Executive Board at Its 109th Session*, EB109/2 (1999).

391. World Health Org., *Smallpox Eradication: Destruction of Variola Virus Stocks, Report by the Secretariat*, A55/21, at 1 (2002); World Health Assembly, Res. 55.15, *supra* note 167, at 1.

392. *See Bush's Comments on His Plan for Smallpox Vaccinations Across the U.S.*, N.Y. TIMES, Dec. 14, 2002, at A12 (noting that the U.S. has stockpiled enough of the smallpox vaccine for the entire population in the event of a biological attack).

393. *See id.*

394. Advisory Comm. on Immunization Practices, *supra* note 359 (discussing how the U.S. terminated automatic smallpox vaccination of military troops in 1990, and continued to vaccinate only selected laboratory and health care workers); TUCKER, *supra* note 95, at 137 (noting that after 1980, U.S. military continued to administer one million smallpox vaccinations per year to new recruits and to other service members at five-year intervals); U.S. DEP'T OF HEALTH & HUMAN SERVS., PROTECTING AMERICANS: SMALLPOX VACCINATION PROGRAM (2002) (explaining that the Department of Defense routinely vaccinated new recruits and veteran service members against smallpox through 1984; but in 1984, vaccination was limited to new recruits, and was intermittent between 1984 and 1990 when it was terminated altogether), *at* http://www.smallpox.gov/VacinationProgramQA.html (last visited Apr. 7, 2003).

395. *See* Dana Hedgpeth, *BioReliance Vs. Bioterrorism*, WASH. POST, Aug. 24, 2000, at E01.

396. *See* D.A. Henderson, *Smallpox: Clinical and Epidemiologic Features*, 5 EMERGING INFECTIOUS DISEASES 537, 538 (1999) ("U.S. national vaccine stocks are sufficient to immunize only 6 to 7 million persons. This amount is only marginally sufficient for emergency needs. Plans are now being made to expand this reserve. However, at least thirty-six months are required before large quantities can be produced."); LeDuc & Becher, *supra* note 153, at 593.

In 1999, the prestigious Working Group on Civilian Biodefense, led by D.A. Henderson at Johns Hopkins University, concluded that the nation's guard had been lowered too far, and recommended procuring forty million new doses of vaccine.[397] At about the same time, government officials undertook to examine the viability of the deteriorating existing stockpile and also to determine whether it could be diluted and thereby stretched to provide adequate vaccine protection to a much larger number of people.[398]

In addition, the government entered into two separate contracts for additional smallpox vaccine production.[399] In 1997, the Department of Defense ordered 300,000 doses for $22.4 million, as part of the expanded Joint Vaccine Acquisition Program to protect troops deploying to high-risk theaters.[400] In 2000, the CDC awarded a $343 million contract for the manufacture of the 40 million doses recommended by the Working Group, with deliveries to begin in 2004 and run through 2020.[401] Remarkably, it was at that time considered difficult, if not impossible, to accelerate the timetable for vaccine production. The few facilities that could manufacture the required amounts

397. Henderson et al., *supra* note 43, at 2136; Judith Miller & Sheryl Gay Stolberg, *Sept. 11 Attacks Led to Push for More Smallpox Vaccine*, N.Y. TIMES, Oct. 22, 2001, at A1 (reporting that the expert group that had originally called for a civilian stockpile of 40 million doses of smallpox vaccine later increased its estimate of the number needed to quell a possible smallpox outbreak to 100-135 million).

398. NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, STUDY SEEKS TO DETERMINE EFFECTIVENESS OF DILUTED SMALLPOX VACCINE (2001), *available at* http://www.niaid.nih.gov/factsheets/btsmallpox.htm (last visited Mar. 15, 2003); LeDuc & Becher, *supra* note 153, at 593.

399. *See* Miller & Stolberg, *supra* note 397 (discussing two contracts for smallpox vaccine, one military contract with Dynport for 300,000 doses to be delivered in 2005 or 2006 and the civilian contract with OraVax for 40 million doses to be delivered after 2004). Reportedly, the Department of Defense refused to share its vaccinia seed stocks with civilian agencies, due to legal impediments (e.g., concerns over product liability) or simple bureaucratic infighting. Brownlee, *supra* note 207.

400. *See Bioterrorism Concerns Spark First Smallpox Vaccine Production in 30 Years*, 3 CBW CHRON., Dec. 2000, at 1; Hedgpeth, *supra* note 395; Miller & Stolberg, *supra* note 397; Preston, *supra* note 144, at 60. The BioReliance contract, which could grow into an order for one million vaccine doses for the military, is a part of a ten-year, $322 million venture between the Department of Defense and DynPort for eighteen vaccines and antidotes against several diseases. *Bioterrorism Concerns Spark First Smallpox Vaccine Production in 30 Years*, *supra*, at 2.

401. *Bioterrorism Concerns Spark First Smallpox Production in 30 Years*, *supra* note 400, at 1; *see also* James W. LeDuc & Peter B. Jahrling, *Strengthening National Preparedness for Smallpox: An Update*, 7 EMERGING INFECTIOUS DISEASES 155, 155 (2001) (noting the increased smallpox vaccine production).

were already under strain, and expansion of their capabilities was widely seen as prohibitively expensive.[402]

After the anthrax scares in October 2001, however, everything changed. Conscious that smallpox could wreck even greater havoc on an unprepared population, the Bush administration immediately announced its intention to seek $509 million in emergency funding, to procure 300 million doses of smallpox vaccine, enough to treat everyone in America, by the end of 2002.[403] The new batch would be manufactured through a modern, cleaner process to avoid some of the problems of the traditional vaccine.[404] Disputes over contracting procedures and feuds between large and small potential bidders threatened to disrupt the acquisition, but new contracts were quickly let to accomplish the goal, and the 2000 CDC contract was also abruptly enlarged, with over fifty million doses somehow now able to be delivered within months.[405]

Fate then intervened in two propitious ways. First, not only was the viability of the existing vaccine inventory confirmed, the experiments in dilution proved successful—what had been seen as stocks suitable to protect at most fifteen million people could now be multiplied five or even ten times.[406] Second, Aventis Pasteur, a French

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402. *See* HENDERSON, *supra* note 175 (noting, in 1999, that "probably not less than two to three years" would be required to construct new facilities to achieve significant levels of smallpox vaccine production), *at* http://www.hopkins-biodefense.org/pages/agents/risk.html; Philip K. Russell, *Vaccines in Civilian Defense Against Bioterrorism*, 5 EMERGING INFECTIOUS DISEASES 531, 532 (1999) (explaining the difficulties associated with producing a new stockpile of the smallpox vaccine).

403. *See* Kristen Hallam & Kim Dixon, *Glaxo, Merck, Baxter Await Smallpox-Vaccine Award*, BLOOMBERG NEWS, Nov. 20, 2001.

404. *See* Rosenthal, *supra* note 90, at 920 (explaining that the traditional vaccine and its method of manufacture would not suffice for modern purity and safety standards).

405. Press Release, U.S. Department of Health and Human Services, HHS Awards $428 Million Contract to Produce Smallpox Vaccine (Nov. 28, 2001), *available at* www.hhs.gov/news/press/2001pres/20011128 (last visited Apr. 7, 2003). The new contract with Acambis/Baxter calls for 155 million vaccine doses to be delivered by the end of 2002 at a cost of $2.76 per dose; in addition, the original 2000 CDC contract with Acambis was accelerated and enlarged to 54 million doses. *Id.*

406. *See* Justin Gillis, *Smallpox Vaccine Supply Could Be Stretched*, WASH. POST, Mar. 29, 2002, at A10 (quoting the director of the National Institute of Allergy and Infectious Diseases as saying that even a tenfold dilution of the vaccine would be safe and effective); Press Release, U.S. Department of Health and Human Services, NIAID Study Results Support Diluting Smallpox Vaccine Stockpile to Stretch Supply (Mar. 28, 2002), *at* http://www.nih.gov/news/pr/mar2002/hhs-28.htm (last visited Apr. 7, 2003). *But see* Sharon E. Frey et al., *Dose-Related Effects of Smallpox Vaccine*, 346 NEW ENG. J. MED. 1275, 1275 (2002) (explaining that the dilution of the smallpox vaccine reduces the chances of an effective vaccination). *See generally* Sharon E. Frey et al., *Clinical Responses to Undiluted and Diluted Smallpox Vaccine*, 346 NEW ENG. J. MED. 1265 (2002) (discussing the experimentation of diluted versus undiluted smallpox vaccinations).

pharmaceutical company, discovered a previously overlooked stockpile of 85 million doses of a similar vaccine in its warehouse in Swiftwater, Pennsylvania and generously donated them to the U.S. government.[407] Suddenly, instead of facing a dangerous shortfall, the United States was awash in smallpox vaccine.[408] Other countries, too, began to follow the American lead, and undertook to procure new vaccinia sources for themselves.[409]

Concomitantly, some worried Americans contemplated or advocated immediate use of those emerging vaccine supplies. They proposed a return to widespread smallpox vaccination—if not a revival of the compulsory nationwide injections of bygone eras, then at least making the protection available to any individual and family who (after being advised of the risks of side effects) affirmatively sought it.[410] Senator Bill Frist (R. Tenn.), the only physician in the U.S. Senate, advocated voluntary vaccination of the general public,[411] and a public opinion poll indicated that sixty percent of the American population would want to be vaccinated if the service were available.[412]

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407. *See* Ceci Connolly, *Aventis to Donate Smallpox Vaccine*, WASH. POST, Mar. 30, 2002, at A02 (stating that Aventis planned to donate 85 million doses); Gina Kolata & Lawrence K. Altman, *Smallpox Vaccine Stockpile Is Larger Than Was Thought*, N.Y. TIMES, Mar. 29, 2002, at A1 (reporting the 85 million dose discovery).

408. *See* Connolly, *supra* note 407. The total U.S. inventory of smallpox vaccine could soon reach as much as 711 million doses: 54 million to be produced under the recently expanded 2000 CDC contract, 155 million under the 2001 HHS contract, 77 million from the five-for-one dilution of the old 15.4 million doses long held in the inventory, and 425 million from a comparable dilution of the newly discovered Aventis Pasteur contribution. *Id.* The inventory would be even greater if the existing vaccine stocks were diluted ten times, instead of five, as the studies have suggested. *See* Martin Enserink, *New Cache Eases Shortage Worries*, 296 SCI. 25, 25 (2002) (discussing the study conducted at St. Louis University which found that smallpox vaccine could be "diluted by a factor of 5 or 10 without losing [its] potency").

409. William J. Broad & Judith Miller, *Others Follow U.S. on Smallpox Vaccine*, N.Y. TIMES, Apr. 25, 2002, at A6; Roy Eccleston, *Washington Offers Allies Protection*, AUSTRALIAN, Dec. 16, 2002, at 11 (discussing how the United States has prepared contingency plans to provide vaccines to Australia and other allies); Tim Harper, *Ottawa Orders 10 Million Anti-Smallpox Doses*, TORONTO STAR, Nov. 28, 2002, at A14 (describing Canada's smallpox vaccination plan). Britain has recently ordered thirty million new doses of vaccine, Israel and Germany six million each, France three million, and other countries smaller amounts. Broad & Miller, *supra*. Israel has already vaccinated seventeen thousand soldiers, health workers, and police against smallpox, with only two people suffering adverse reactions, and will soon expand the program to reach forty thousand people. Dexter Filkins, *Israel Will Expand Its Smallpox Vaccinations, but Not To Everyone*, N.Y. TIMES, Dec. 26, 2002, at A23.

410. *See* Bill Frist, *Deciding Who Is To Be Protected Against Smallpox*, N.Y. TIMES, Aug. 9, 2002, at A15 (suggesting that Americans be given the opportunity to make informed decisions about being vaccinated).

411. *Id.*

412. Veronique de Rugy & Charles V. Peña, *Responding to the Threat of Smallpox Bioterrorism: An Ounce of Prevention Is Best Approach*, POL'Y ANALYSIS, Apr. 18, 2002, at 1, 8-9; *see also*

Still, the WHO, the CDC, and other health officials steadfastly counseled against any return to mass vaccination, arguing that the dangers of the vaccine's side effects meant that the traditional surveillance-containment strategy "remains the best method of stopping a smallpox outbreak."[413] Experts suggested that the existing vaccine would be contraindicated for up to twenty-five percent of the American population and that no vaccination should be offered to anyone who had close household contact with someone for whom even indirect exposure to vaccinia was contraindicated.[414] They calculated that a nationwide vaccination program might result in 180-600 deaths, thousands of severe illnesses, and days of lost work time for up to thirty percent of those vaccinated.[415] A substantial debate then erupted in both scientific and public forums.[416]

Bicknell, *supra* note 175, at 1323-24; Robert J. Blendon et al., *The Public and the Smallpox Threat,* 348 NEW ENG. J. MED. 426, 428 (2003); Ceci Connolly, *Some Want Smallpox Shots Now,* WASH. POST, Dec. 26, 2001, at A01; Associated Press, *Most Americans Want Smallpox Vaccination,* WASH. TIMES, Nov. 19, 2001, at A8. However, others do not favor a widespread vaccination campaign. *See* Gina Kolata, *With Vaccine Available, Smallpox Debate Shifts,* N.Y. TIMES, Mar. 30, 2002, at A8 (describing how public sentiment can easily turn against vaccination programs when the dangers of the vaccine appear greater than the actual threat of the disease).

413. Press Release, World Heath Organization, World Health Organization Announces Updated Guidance on Smallpox Vaccination (Oct. 2, 2001), *available at* http://www.who.int/inf-pr-2001/en/state2001-16.html (last visited Apr. 8, 2003); *see also* Advisory Comm. on Immunization Practices, *supra* note 412, at 18-20 (recommending smallpox vaccination only for specific groups). *But see* de Rugy & Peña, *supra* note 412, at 5-6 (arguing that ring vaccination strategy is not appropriate for countering a terrorist attack where the population at large is unvaccinated); Michael Scardaville, *Public Health and National Security Planning: The Case for Voluntary Smallpox Vaccination,* HERITAGE FOUND. BACKGROUNDER, Dec. 6, 2002, at 1, 3-4 (suggesting postattack vaccination would not suffice to deal with modern bioterrorism).

414. Susan Okie, *Studies Cite Smallpox Vaccine Tradeoff,* WASH. POST, May 8, 2002, at A03 (estimating that 25% of the U.S. population would be ineligible for vaccination, including those who live with anyone in a high-risk group); *see also* Lawrence K. Altman, *Smallpox Vaccinations Urged for Health Care Workers,* N.Y. TIMES, June 7, 2002, at A24 (stating as many as thirty-eight million Americans could be a risk from vaccine complications).

415. *See* Bicknell, *supra* note 175, at 1324 (discussing the mortality and complication effects of smallpox vaccination); Julie Kosterlitz, *Who Counts?,* 34 NAT'L J. 1296, 1302 (2002) (stating up to 500 people may die from the vaccine); de Rugy & Peña, *supra* note 412, at 6-8 (suggesting that vaccinating the entire U.S. population could lead to up to 600 deaths and 2000 individuals with serious brain infections); Peter Gorner & Christi Parsons, *Some Wary of State Plan for Smallpox Vaccinations,* CHI. TRIB., Dec. 10, 2002, at N1 (noting that the CDC estimates around 30% of vaccinated people will feel too sick to work).

416. *See* Bicknell, *supra* note 175, at 1323; Anthony S. Fauci, *Smallpox Vaccination Policy—The Need for Dialogue,* 346 NEW ENG. J. MED. 1319, 1319-20 (2002); Paul W. Ewald, *A Risky Policy on Smallpox Vaccination,* N.Y. TIMES, Dec. 17, 2001, at A21 (discussing voluntary vaccinations); *How to Prepare for a Smallpox Attack,* N.Y. TIMES, June 23, 2002, § 4, at 12; Katz, *supra* note 168; Reuters, *Mass Inoculations Opposed,* N.Y. TIMES, Dec. 5, 2001, at B5 (reporting that the American Medical Association opposes mass smallpox vaccination).

In June 2002, the CDC's key Advisory Committee on Immunization Practices recommended only a small expansion of prior vaccination programs: treat two specific categories of health officials in each state. These categories should include teams of officers who would be dispatched immediately to investigate a possible smallpox outbreak, and groups of hospital workers who would be designated to treat the initial victims.[417] These might total 15,000-20,000 "first responders" nationwide, who would be carefully screened for contraindications and vaccinated on a voluntary basis.[418] By October, however, the committee had reconsidered the situation, and recommended expanding the program to reach as many as 500,000 primary health workers in half the nation's hospitals.[419]

The federal government, however, has aimed more than an order of magnitude higher: it proposes to vaccinate some eleven million soldiers, firefighters, police officers, emergency room staffs, and private practitioner doctors and nurses in a multi-step process.[420] As announced by President Bush on December 13, 2002, the first phase of the plan mandates the vaccination—already well underway—of half a million military service members, especially those in special forces units and those deploying to high-threat areas such as the Middle East.[421] In January 2003, when new legislation was enacted protecting hospitals against legal liability for adverse reactions, voluntary vaccina-

417. Lawrence K. Altman, *Smallpox Proposal Raises Ethical Issues*, N.Y. TIMES, June 22, 2002, at A9.

418. *Id.* After the termination of routine smallpox vaccination in the 1980s, the vaccine was confined to only a limited number of researchers who actively work with the virus; since 1983, eleven thousand people have received the vaccination. *Id.*

419. *See* David Brown, *Panel Alters Advice on Smallpox Shots; Wider Use for Health Workers Backed*, WASH. POST, Oct. 17, 2002, at A03; David Brown, *Panel Leery of Mass Smallpox Doses; Major Risks Outweigh Benefits of Immunizing the General Public, Experts Say*, WASH. POST, Oct. 18, 2002, at A02; Ceci Connolly, *2 Hospitals Refuse Call to Vaccinate Workers*, WASH. POST, Dec. 18, 2002, at A02.

420. *Bush's Comments on His Plan for Smallpox Vaccinations Across the U.S.*, *supra* note 392; Stevenson & Stolberg, *supra* note 91; U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 394, *at* http://www.smallpox.gov/VaccinationProgramQA.html.

421. *See* Associated Press, *1st Vaccinations Show 1 in 3 Soldiers Exempt*, NEWSDAY, Dec. 21, 2002, at A10 (reporting that in the earliest round of vaccinations of members of the military's smallpox response teams, 37% of those screened were ineligible for vaccination, either because of their own contraindications or because they lived with someone who would be at risk from side effects of exposure to vaccinia); Denise Grady, *Pentagon Faces Difficulties in Smallpox Shots for Troops*, N.Y. TIMES, Dec. 17, 2002, at 20 (noting problem of vaccinated and unvaccinated service members working and living in close proximity, where the vaccinia infection might spread to those for whom it is contraindicated). Early vaccination will also be offered to selected Department of State employees who are posted to vulnerable overseas locations. Press Release, The White House, Protecting Americans: Smallpox Vaccination Program (Dec. 13, 2002), *at* http://whitehouse.gov/news/releases/2002/12/20021213_1.html (last visited Feb. 1, 2003).

tion began for 500,000 hospital workers and the staffs of local health departments.[422] However, resistance from a variety of hospitals, health workers' unions and others delayed the program; only a small fraction of the anticipated vaccination coverage was achieved on schedule. Additional legislation, to ensure financial compensation for those injured by adverse reactions to vaccinia, may now encourage greater participation.[423] The next phase, originally earmarked for March 2003 but now also delayed, calls for voluntary vaccination of a full ten million health care workers, police, firefighters, and emergency medical technicians across the country.[424] By late 2003 or 2004, smallpox vaccine would also be made available, for free, to private citizens who "insisted" upon vaccination, although federal authorities still strongly recommend against that step at this time.[425]

In addition, the government's program creates a robust infrastructure designed to expedite the delivery and application of smallpox vaccinations for the general public in the event of any future massive attack.[426] Each state and the largest municipalities have been charged to develop plans for voluntary large-scale administration of vaccine to their entire populations—up to one million doses are to be applied by each unit within the first ten days of an emergency. The Centers for Disease Control has begun to review and comment upon those draft plans, as well as to distribute its own guidance on details ranging from what to tell the public to how many security guards a vaccination station should expect to hire.[427]

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422. *See* Lawrence K. Altman & William J. Broad, *Vaccination; State Officials Question Smallpox Timetable*, N.Y. TIMES, Dec. 13, 2002, at A1; *see also* Lawrence K. Altman, *The Bioterrorism Threat; Health Workers Union Wary of Smallpox Vaccinations*, N.Y. TIMES, Dec. 10, 2002, at A23 (reporting a health care workers union's concern that a sufficient legal regime was not in place to address vaccine-related problems).

423. Ceci Connolly, *Lawmakers, White House Agree on Smallpox Compensation*, WASH. POST, Apr. 11, 2003, at A11; Ceci Connolly, *U.S. Smallpox Vaccine Program Lags*, WASH. POST, Apr. 13, 2003, at A03.

424. Stevenson & Stolberg, *supra* note 91.

425. *See id.* (stating a new FDA-licensed version of the vaccine might be available to the general public in 2004, but also explaining that HHS Secretary Tommy G. Thompson promised to pursue "an orderly process" for making the current vaccine available to the public, too, perhaps in summer 2003); *see also* Lawrence K. Altman & Denise Grady, *The Vaccine; Smallpox Shot Will Be Free for Those Who Want One*, N.Y. TIMES, Dec. 15, 2002, § 1, at 38 (explaining Secretary Thompson's vaccination plan).

426. *See generally* U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, SMALLPOX VACCINATION CLINIC GUIDE Annex 3 (2002) (providing a model plan for high volume "post-event" smallpox vaccinations).

427. Press Release, U.S. Centers for Disease Control, CDC Initial Review of State Smallpox Vaccination Plans Complete (Dec. 12, 2002), *available at* http://www.cdc.gov/od/oc/media/pressrel/r021212.htm (last visited Apr. 9, 2003); *see also* Altman & Broad, *supra* note 422 (noting that on initial review, CDC finds draft plans encouraging); William J. Broad,

President Bush, as the military commander-in-chief, was one of the first to receive the smallpox vaccination, but he stressed that civilians, including his own family, his immediate staff, the cabinet, and members of Congress, would not be vaccinated at that time.[428] Concomitantly, the federal government undertook a massive outreach campaign to educate the medical community and the public about bioterrorism in general and smallpox in particular[429]—an effort that surveys revealed was desperately needed, in light of the general misinformation and apprehension that had gripped the country.[430]

Still, the medical community was sharply divided about the wisdom of the proposed program, and some hospitals rejected vaccinating their staffs because they worried the injections would cause widespread absenteeism due to adverse reactions, and employees might inadvertently communicate vaccinia infections to their patients, who were among the most vulnerable populations.[431] The unknown effect of the vaccine on children was also a source of great, unresolved, and perhaps untestable concern.[432]

U.S. Guide for Mass Smallpox Vaccinations: Recipe with Missing Ingredients, N.Y. TIMES, Sept. 24, 2002, at A19 (revealing omissions in the CDC's guidelines); Sheryl Gay Stolberg & Lawrence K. Altman, *The Plan; New Plan to Meet Smallpox Attack*, N.Y. TIMES, Sept. 24, 2002, at A1 (discussing the CDC's smallpox vaccination guidelines).

428. Stevenson & Stolberg, *supra* note 91 (commenting that even Vice President Dick Cheney will not be vaccinated unless a smallpox attack occurs).

429. *See* Press Release, U.S. Department of Health and Human Services, Comprehensive Information Provided on www.smallpox.gov (Dec. 13, 2002) (announcing a new website for providing current information to the public and the medical community), *at* http://www.hhs.gov/news/press/2002pres/20021213.html); *see also* Altman & Grady, *supra* note 425 (reporting that CDC is preparing to send 150,000 educational CD-ROMs to doctors and to train 140 thousand through other programs).

430. Blendon et al., *supra* note 412, at 426 (concluding most Americans hold erroneous beliefs about several critical smallpox facts and issues); Denise Grady, *Bioterrorism; Scientists Favoring Cautious Approach to Smallpox Shots*, N.Y. TIMES, Dec. 20, 2002, at A1 (noting public ignorance or misperception about basic facts concerning smallpox and vaccination).

431. *See* Kent A. Sepkowitz, *How Contagious Is Vaccinia?*, 348 NEW ENG. J. MED. 439, 443-45 (2003) (discussing the risk of secondary transmission, through which health care workers may accidentally infect their patients, especially those with compromised immune systems); Altman & Broad, *supra* note 422 (noting that some state officials and medical authorities argue that they need more time to prepare for and carry out the ambitious vaccination program); Connolly, *supra* note 419 (reporting Grady Memorial Hospital in Atlanta and Virginia Commonwealth Hospital in Richmond refused to vaccinate their employees against smallpox); Vicki Kemper & Rosie Mestel, *Medical Groups Criticize Bush's Smallpox Plan*, L.A. TIMES, Dec. 20, 2002, § 1, at 32 (alleging the government's smallpox vaccination program will strain public health resources and pose health risks to medical personnel); William Foege, *Can Smallpox Be as Simple as 1-2-3?*, WASH. POST, Dec. 29, 2002, at B05 (stating there is mixed reaction to President Bush's smallpox plan).

432. *See* Altman & Grady, *supra* note 425 (noting the smallpox vaccination has not been tested on children); Donald G. McNeil Jr., *Citing Dangers, Experts Warn Against Vaccinating Children*, N.Y. TIMES, Dec. 13, 2002, at A27 (reporting the vaccine may be most dangerous

B. *National Security*

The alterations in American security policy have been likewise profound since the hijacked airliners slammed into the World Trade Center and the Pentagon. The United States is fighting terrorists and their state sponsors in Afghanistan, Iraq, and elsewhere; the Department of Homeland Security has been created to help craft a more coordinated national strategy for domestic protection;[433] and additional funding is pouring into a wide variety of new and previously overlooked needs for protective personnel, training and equipment.[434]

The incipient threat of *biological* terrorism, in particular, has energized much of the response. Money is now thrown at programs to interdict the newly appreciated danger, at the same time that the community realizes its awesome vulnerability to conspiracies as simple and as deadly as mailed anthrax spores. The wail of: "Why weren't we warned about this—why weren't we prepared?" has already begun to soften, as we appreciate that terrorism experts were, in fact, long sounding a futile alarm, and that to a large extent, we can never be fully insulated against these types of assaults.[435] In fact, the most haunting unanswered questions now may be: "Why didn't it happen sooner?" and "Where will it happen next?"

Simulation exercises in recent years have validated the profound concerns about American vulnerability to BW in general, bioterrorism more specifically, and smallpox in particular. Most prominently, a 2001 program denominated "Dark Winter" collected a panel of experienced senior government officials and challenged them with a hypothetical smallpox outbreak involving three two-person teams dispensing variola via simple aerosol spray devices at shopping malls

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for children and teenagers, and ethical constraints may prohibit testing it to determine its true level of risk); Sheryl Gay Stolberg, *Proposal to Test Smallpox Vaccine in Young Children Sets off Ethics Debate*, N.Y. TIMES, Nov. 5, 2002, at A14 (discussing a proposed pediatric smallpox vaccination trial and related ethical questions and risks).

433. *See* Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2135 (creating the Department of Homeland Security).

434. *See, e.g.*, Lawrence K. Altman, *U.S. Sets Up Plan to Fight Smallpox in Case of Attack*, N.Y. TIMES, Nov. 4, 2001, at 1A (reporting that the CDC has vaccinated 140 members of epidemiologic teams that could be dispatched immediately to deal with a smallpox outbreak). The CDC also has instituted a variety of professional training programs to assist health workers in identifying and responding to smallpox cases, and it has increased physical security at its Atlanta headquarters. *Id.*

435. Sheryl Gay Stolberg & Judith Miller, *Many Worry That Nation Is Still Highly Vulnerable to Germ Attack*, N.Y. TIMES, Sept. 9, 2002, at A16 (stating that regardless of the amount of money and preparation, most public health and intelligence officials agree "the nation will never be fully prepared for or protected against a biological attack").

in Oklahoma City, Atlanta, and Philadelphia.[436] In the simulation, even this expert group quickly lost control of the situation: by the sixth day of the program, the nation's entire vaccine stockpile was exhausted. By the end, thirteen days later, the disease had spread to twenty-five states and fifteen foreign countries, 2600 people had died, and another 11,000 were infected, with no end in sight.[437] More than 200 other comparable counter-terrorism exercises, simulations, or computer models have been run for a variety of federal, state, and local officials with disparate, but often equally disconcerting results.[438]

At the same time, the Bush administration seems even more stridently attached to a foreign policy of unilateralism—a willingness, even an eagerness, to "go it alone" in international affairs, even if other countries, including our closest traditional allies, urge a different tack that might entail some compromise of America's solo preferences.[439] While trying to assemble a broad international coalition for action against al Qaeda and other terrorists,[440] the United States has not reciprocated by acknowledging other countries' interests or concerns on a vast set of global agenda items.[441] A wide array of treaties

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436. Roxanne Roberts, *A War Game To Send Chills Down the Spine*, WASH. POST, Oct. 23, 2001, at C01.

437. *See* ANSER INST. FOR HOMELAND SEC., DARK WINTER, *at* http://www.homelandsecurity.org/darkwinter (last visited Apr. 9, 2003); *see also* Martin Enserink, *How Devastating Would a Smallpox Attack Really Be?*, 296 SCI. 1592, 1592-94 (2002) (discussing the Dark Winter simulation and related critique); Reuters, *U.S. Called Vulnerable to Biological Attack; Smallpox Simulation Alarms Officials*, WASH. POST, July 24, 2001, at A05 (describing the simulation). Analysts have generated other models of disease outbreak that are far less pessimistic than the results of the Dark Winter exercise. William J. Broad, *Study Favors Different Track on Smallpox*, N.Y. TIMES, July 9, 2002, at A17

438. *See, e.g.*, Joby Warrick & Steve Fainaru, *Bioterrorism Preparations Lacking at Lowest Levels; Despite Warnings and Funds, Local Defenses Come Up Short*, WASH. POST, Oct. 22, 2001, at A07 (explaining that funding for the more than 200 counterterrorism training exercises conducted by the federal government came from the 1996 Defense Against Weapons of Mass Destruction Act). *See also* Thomas V. Inglesby et al., *A Plague on Your City: Observations from TOPOFF*, 32 CLINICAL INFECTIOUS DISEASES 436, 436-37, 443-44 (2001) (explaining that "Operation TOPOFF 2000"—so designated because it was designed to train "top officials" of the U.S. government—was the largest simulation exercise of its kind to date). TOPOFF included three simultaneous crises: a chemical weapons event in Portsmouth, NH, a radiological event near Washington, D.C., and a bioweapons event involving the bacteria that causes plague in Denver. *Id.* The exercise revealed vulnerabilities in many areas, including problems of leadership and decision-making, poor prioritization and distribution of scarce human and pharmacological resources, and the overwhelming of hospitals and other health care facilities. *Id.*

439. *See* Steven Erlanger, *Europe Seethes as the U.S. Flies Solo in World Affairs*, N.Y. TIMES, Feb. 23, 2002, at A8.

440. David E. Sanger & Michael R. Gordon, *U.S. Takes Steps to Bolster Bloc Fighting Terror*, N.Y. TIMES, Nov. 7, 2001, at A1.

441. *See* Barbara Crossette, *Washington Is Criticized for Growing Reluctance to Sign Treaties*, N.Y. TIMES, Apr. 4, 2002, at A5.

on anti-personnel landmines,[442] the International Criminal Court,[443] global climate change,[444] nuclear test ban,[445] children's rights,[446] the law of the sea,[447] and other matters has received widespread acclaim and overwhelming multilateral support.[448] Yet, the United States has rigidly stayed away from each of them when American priorities were not fully satisfied.[449]

The proposed protocol to the Biological Weapons Convention provides yet another important illustration of this worrisome trend. That proffered instrument, the product of a decade of incremental give-and-take, is hardly perfect. The ineffable tradeoff it makes between openness (to enhance confidence that other countries are not violating the obligations) and privacy (to protect defense-oriented national security information, as well as corporate confidential business data from abusive intrusions), can always be second-guessed.[450] Moreover, the BWC, an agreement between sovereign states, will inherently have relatively little to do with terrorism by private actors. The treaty regulates behavior by and between countries, and was not crafted with insidious non-state actors principally in mind.

Still, it came as a surprise and a disappointment in 2001 when the Bush administration so curtly rejected the draft protocol, and even more so when it subsequently undertook to pull the plug on the entire negotiation process. That highhanded approach generated considerable acrimony, and the rest of the world has continued to advocate an ambitious, legally-binding protocol, instead of the lesser measures envisioned by the United States.[451] A one-year "cooling off period" sufficed to avert an immediate diplomatic train wreck, and the negotiators paused to consider Washington's new set of much more modest proposals for BW arms control and to attempt to find a mechanism to accommodate the evolving American positions.[452]

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442. *Id.*

443. *Id.*

444. *Id.*

445. *Id.*

446. *Id.*

447. Jeffrey Gedmin & Gary Schmitt, *Allies in America's National Interest*, N.Y. TIMES, Aug. 5, 2001, § 4, at 13.

448. Crossette, *supra* note 441.

449. Gedmin & Schmitt, *supra* note 447.

450. *See supra* notes 253-257 and accompanying text (discussing U.S. reluctance to support verification measures).

451. *See* Elizabeth Olson, *U.S. Rejects New Accord Covering Germ Warfare*, N.Y. TIMES, July 26, 2001, at A7.

452. *See* Tucker & Zilinskas, *supra* note 256, at 10; Jonathan B. Tucker, *In the Shadow of Anthrax: Strengthening the Biological Disarmament Regime*, NONPROLIFERATION REV., Spring 2002, at 112, 113-14.

The Bush administration has proclaimed its continuing interest in deriving new international methods to combat the accelerating threats of biological warfare and bioterrorism, but in November 2002, the hard-line American stance led to abandonment of the negotiators' effort to draft a new treaty or even a consensus report detailing their frustrated efforts.[453] Annual diplomatic meetings, expected to be truncated and minimally effective, will continue through 2005 with a limited set of mandates and with little prospect for a universally acceptable protocol.[454] Some portions of the recent U.S. suggestions for a revised accord may provide a basis for further deliberations,[455] but only if the Bush administration would be willing to return to the negotiating table and attempt to hammer out a new consensus.

Domestically, the federal government has redoubled its efforts to interdict the dangers of bioterrorism, and state and local governments also have injected new energy and resources into the problem.[456] New legislation has facilitated the development of adequate emergency response algorithms, and additional training and resources have been showered upon the community's potential first responders, empowering them to plan more conscientiously for the worst contingencies.[457] Observers conclude that the United States is now much better prepared to identify and react appropriately to a BW attack, especially a smallpox terrorism incident, but none could yet be satisfied with the still-evolving precautions.[458]

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453. *See* Peter Slevin, *U.S. Drops Bid To Strengthen Germ Warfare Accord*, WASH. POST, Sept. 19, 2002, at A01 (reporting U.S. attempt to preclude additional negotiations on a BWC protocol until 2006).

454. *See id.* (reporting Undersecretary of State John R. Bolton as suggesting that instead of negotiating an ambitious treaty, countries should develop their own criminal laws against germ warfare and resolve disputes over biowarfare violations through inspections conducted by the United Nations secretary general).

455. U.S. DELEGATION TO THE 5TH REVIEW CONFERENCE OF THE BWC, FACT SHEET: U.S. EFFORTS TO COMBAT THE BIOLOGICAL WEAPONS THREAT (Nov. 14, 2002), *at* http://usinfo.state.gov/topical/pol/terror/02111405.htm (last visited Apr. 10, 2003); *see also* Oliver Meier, *Bare-Bones Multilateralism at the BWC Review Conference*, ARMS CONTROL TODAY, Dec. 2002, at 19.

456. *See* Davidson, *supra* note 292 (citing dramatically increased supplies of vaccine and improved readiness among local and state health officials).

457. *Id.*

458. *See id.* (quoting D.A. Henderson as saying, "It's been miraculous. We now feel much better than we did a year ago" regarding the ability to spot and combat a smallpox outbreak); *see also* Ronald Bayer & James Colgrove, *Public Health vs. Civil Liberties*, 297 SCI. 1811, 1811 (2002) (describing model legislation to enable state governments to respond to bioterrorism without unduly impinging personal freedoms); Marilyn Werber Serafini, *Tulsa Gears Up for Bioterrorism*, 34 NAT'L J. 2613 (2002) (discussing Tulsa's monitoring and readiness plan); Geoffrey Cowley, *The Plan to Fight Smallpox*, NEWSWEEK, Oct. 14, 2002, at 44 (reviewing government plans for preparing against a potential smallpox attack); Stephen

The most recent federal enactment is the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.[459] The Act broadly undertakes to improve emergency communication between federal, state, and local health agencies, to mandate the development of a comprehensive national plan to combat sudden disease outbreaks, to train and educate public health professionals to recognize bioterrorism incidents, and to fund a $1.2 billion expansion of the stockpile of vaccines and drugs.[460] In addition, the new law aims to tighten security measures at biotechnology facilities and restricts access to several dozen of the most dangerous pathogens, screening out potential users with suspected terrorist connections.[461] Despite its aggressive reach, the enactment has been received relatively warmly by the facilities it governs, even by the 190,000 manufacturers, laboratories, and individual scientists who will now have to register as holding any of the identified "select agents."[462]

At this point, it is abundantly clear to all that the struggle against bio-terrorism will be long, difficult, and multi-faceted. The process also provides a timely reminder about the dangers of hubris: no security system, even one tightly calibrated to respond to the new threats, can ever be perfect. In April 2002—a time when federal security personnel and physical control systems should have been upgraded to meet the highest standards—a test conducted by the U.S. General Ac-

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Smith, *US Plans a System to Detect Bioattack*, BOSTON GLOBE, Oct. 3, 2002, at A1 (reporting Centers for Disease Control is planning a computerized surveillance system to monitor the national demand for key pharmaceuticals that could signal an outbreak of smallpox or other bioterrorism).

459. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594.

460. Public Health Security and Bioterrism Preparedness and Response Act of 2002 §§ 101, 121.

461. Public Health Security and Bioterrism Preparedness and Response Act of 2002 § 201; *see also* Interstate Shipment of Etiological Agents , 42 C.F.R. § 72, appendix A (2002); Possession, Use and Transfer of Biological Agents and Toxins; Interim Final Rule, 67 Fed. Reg. 76,908 (Dec. 13, 2002) (to be codified at 7 C.F.R. pt. 331 & 9 C.F.R. pt. 121) (providing regulations for the Department of Agriculture); Possession, Use, and Transfer of Select Agents and Toxins; Interim Final Rule, 67 Fed. Reg. 76,886 (Dec. 13, 2002) (to be codified at 42 C.F.R. pts. 73, 1003) (providing regulations for the Department of Health and Human Services); Preliminary Guidance for Notification of Possession of Select Agents; Notice, 67 Fed. Reg. 46,363 (July 12, 2002).

462. *See* Virginia Gewin, *Scientists Placated as US Bill Gets Tough on Bioterror*, 417 NATURE 475 (2002) (reporting that many scientists are happy with the new legislation); *see also* Diana Jean Schemo, *After 9/11, Universities Are Destroying Biological Agents*, N.Y. TIMES, Dec. 17, 2002, at A20 (reporting some laboratories are destroying their inventories of select agents, potentially compromising future research undertakings, rather than register them under the new statute and regulations); Diana Jean Schemo, *Sept. 11 Strikes at Labs' Doors*, N.Y. TIMES, Aug. 13, 2002, at F1 [hereinafter *Sept. 11 Strikes*] (noting that some scientists are concerned regarding the secrecy mandate).

counting Office demonstrated the extent of the ongoing problem. In that experiment, a number of sophisticated, knowledgeable intruders easily evaded the perimeter and inner security at four major federal buildings in Atlanta, Georgia, the home city of the Centers for Disease Control and its variola virus stockpile.[463] The testers repeatedly fooled guards into providing them with security passes and after-hours codes, allowing them to enter and exit the supposedly secure facilities with packages that were not examined by X-ray or magnetometers.[464] The CDC itself was not one of the four buildings targeted in the experiment,[465] and no challenges have been levied about the security of the variola inventory and other hazardous pathogens housed there, but one cannot be confident that such a shocking breach could never occur.

The latest word regarding the possible threat of smallpox bioterrorism in the United States, and on the rising levels of that danger, came in President Bush's December 2002 announcement of his revised plan for smallpox vaccinations.[466] Sounding notes of both reassurance and caution, he asserted, "Our government has no information that a smallpox attack is imminent. Yet it is prudent to prepare for the possibility that terrorists would kill indiscriminately, who do kill indiscriminately, would use diseases as a weapon."[467]

C. *Science*

Variola researchers have intensified their investigatory efforts, continuing to make incremental, but inexorable, progress in their quest to uncover more of their target's potent secrets. First, the existing viral inventory has been surveyed and catalogued with greater precision than ever before.[468] We now have a much better idea of what sorts of materials are held in the CDC and Vector, how different

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463. *Security Breaches at Federal Buildings in Atlanta, Georgia: Testimony Before House Comm. on Government Reform*, 108th Cong. 1-3 (2002) [hereinafter *Security Breaches at Federal Buildings*] (statement of Ronald Malfi, Acting Managing Director, Office of Special Investigations, U.S. General Accounting Office).

464. *Id.*; *see also* David Firestone, *Investigators Breach Security in 4 U.S. Buildings in Atlanta*, N.Y. TIMES, May 1, 2002, at A18.

465. *Security Breaches at Federal Buildings*, *supra* note 463.

466. *Bush's Comments on His Plan for Smallpox Vaccinations Across the U.S.*, *supra* note 392; William J. Broad, *Bush Signals He Thinks Possibility of Smallpox Attack Is Rising*, N.Y. TIMES, Dec. 14, 2002, at A13.

467. *Bush's Comments on His Plan for Smallpox Vaccinations Across the U.S.*, *supra* note 392.

468. World Health Organization, Smallpox Eradication: Destruction of Variola Virus Stocks, A55/21 (Apr. 5, 2002); World Health Organization, Smallpox Eradication: Temporary Retention of Variola Virus Stocks, A54/16 (Apr. 11, 2001) (stating that since 2001, 50 more isolates from the Russian collection were studied).

they are from each other, and how many of them may remain viable. Second, the task of revealing the virus's genetic sequence has progressed more swiftly than originally contemplated; no fewer than ten diverse strains have now been thoroughly mapped.[469]

The leading candidate antiviral medication, cidofovir (or its improved version, known as hdp-cdv) has fared well in *in vitro* tests in the past year.[470] It is now accepted as an Investigational New Drug by the FDA, and may proceed soon to evaluation in animal models.[471] No fewer than 270 other potential antivirals have been assayed in cell cultures, and 140 were selected for additional screening.[472] Progress in pursuit of a new vaccine was likewise described as encouraging, especially regarding a weakened strain of vaccinia called Modified Vaccinia Ankara (MVA), but no immediate breakthroughs are yet at hand.[473] Other tantalizing innovations in combating variola have also been sketched out, but not yet fully developed.[474] An important enabling step in support of these and other future projects is the development of a suitable animal model for studying smallpox and its

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469. *E.g.*, World Health Organization, Smallpox Eradication: Destruction of Variola Virus Stocks, *supra* note 468, at 3 (reporting that ten full-length variola isolate genomes had been identified as of April 2002).

470. World Health Organization, Smallpox Eradication: Destruction of Variola Virus Stocks, *supra* note 468, at 4 (discussing cidofovir effectiveness against cowpox and monkeypox and possible use with current smallpox vaccines); *see* James E. LeDuc et al., *Smallpox Research Activities: U.S. Interagency Collaboration, 2001*, 8 EMERGING INFECTIOUS DISEASES 743 (2002) (summarizing the results of a variola research collaboration between the CDC and the National Institutes of Health).

471. *See, e.g.*, LeDuc et al., *supra* note 470, at 743 (stating that an Investigational New Drug application was filed for cidofovir in 2001).

472. *Id.* at 744 (reporting that over 700 possible antivirals have been screened *in vitro* and stating that of those which show promise, more than 20 will be tested on animals); James E. LeDuc & Peter G. Jahrling, *Strengthening National Preparedness for Smallpox: An Update*, 7 EMERGING INFECTIOUS DISEASES 155, 156 (2001) (reporting that 274 antiviral compounds were screened for therapeutic activity against variola).

473. Cowley, *supra* note 458, at 44 (noting that "MVA is the most promising third generation vaccine); Steven Sternberg, *Researchers on the Trail of a Better Smallpox Vaccine*, U.S.A. TODAY, Dec 26, 2002, § LIFE, at 7D (observing that immune responses are the same for the live-virus vaccine and MVA, and MVA is safe enough to use on people with HIV and AIDS).

474. Sternberg, *supra* note 473 (setting forth possibilities such as using MVA to make standard vaccine safer, a Japanese vaccine grown at seven degrees cooler than body temperature, and dead vaccinia with chemicals to boost immunity); *see also* Rosenthal et al., *supra* note 90, at 920 (describing vaccine production options and their associated efficacy and safety); Henry I. Miller & David Longtin, *Don't Offer All Americans Smallpox Vaccinations Now*, USA TODAY, Nov. 20, 2002, at 15A (noting that pharmaceutical companies are developing a variety of poxvirus-based vaccines against HIV as well as therapies against cancer and warning that those receiving the smallpox vaccine may develop long-term immunity against related viruses that will interfere with those novel treatments); Jeff Nesmith, *Artificial Antibody Might Thwart Smallpox*, ATLANTA J. & CONST., Oct. 17, 2002, at 4A (revealing that researchers have identified an antibody that may be useful as an anti-smallpox tool).

potential therapies. Researchers have registered success in inducing a variant of the disease in cynomolgus monkeys for this purpose.[475] Also noteworthy is the uptick in cooperation between the two WHO Smallpox Collaborating Centers, as American, Russian, and other experts have shared projects and further subsidized Vector's ongoing conversion to fully civilian operations.[476]

Advances in the broader field of genetic engineering have also progressed at a breathtaking pace. Most dramatically, researchers at the State University of New York at Stony Brook (financed by the U.S. Department of Defense) succeeded for the first time in July 2002 in synthesizing a live virus.[477] They assembled viable polio viruses by combining raw chemicals step-by-step, following the publicly available genetic sequence data.[478] By crafting a functional pathogen "from scratch,"[479] the scientists have demonstrated the ability to elicit artificial life from nature's basic building blocks (which are now inexpensively available by mail order), thereby validating a technique that some said could be applied to other pathogens with relative ease and speed and at surprisingly low cost.[480]

Commentators disagreed about how readily the feat could be performed on variola, whose DNA chain is many times longer and more complex than polio's. Yet articulation of that technology certainly calls into question the logic of destroying the CDC and Koltsovo samples. If endless inventories of new variola could some day be generated artificially in standard molecular biology laboratories, what would

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475. LeDuc et al., *supra* note 470, at 744-45 (stating that earlier efforts with cynomolgus monkeys did not produce a disease sufficiently similar to human smallpox, but more recent tests indicate a successful animal model is possible); David Ruppe, *Smallpox: U.S. Army Derives Controversial Primate Host, Possible Bio-Defense Breakthrough*, GLOBAL SECURITY NEWSWIRE, Jan. 24, 2002 (observing that exposing primates to high concentrations of aerosolized smallpox resulted in only slight infection), *at* http://www.nti.org/d_newswire/issues/2002/1/24/10p.html (last visited Apr. 9, 2003).

476. *See* World Health Organization, Smallpox Eradication: Temporary Retention of Variola Virus Stocks, *supra* note 468, at 2 (observing that advanced cooperation between VECTOR and the CDC has begun); WORLD HEALTH ORGANIZATION, WHO ADVISORY COMMITTEE ON VARIOLA VIRUS RESEARCH, *supra* note 468, at 2 (cooperation between the two Centers includes transfer of biological reagents).

477. Erika Check, *Poliovirus Advance Sparks Fear of Data Curbs*, 418 NATURE 265, 265 (2002).

478. *Id.*

479. Rick Weiss, *Polio-Causing Virus Created in N.Y. Lab*, WASH. POST, July 12, 2002, at A01.

480. *Id.* (noting that synthesizing a virus may cost only around $10,000); *see also* Andrew Pollack, *Scientists Create a Live Polio Virus*, N.Y. TIMES, July 12, 2002, at A1 (reporting that Dr. Eckard Wimmer, the lead scientist of the team that synthesized the polio virus, stated that they had made the virus in part as a warning of possible terrorist capabilities); Sylvia Pagan Westphal, *How to Make a Killer Virus*, NEW SCIENTIST, July 20, 2002, at 6 (stating that the steps followed by scientists who made the polio virus can be replicated by terrorists).

be the point of eradicating the last natural stocks? The prescient 1999 Institute of Medicine report had contemplated the possibility of just such developments, noting that the step-by-step building of active variola might soon be mechanically feasible, and adding, "There is no way of predicting the rate at which such technologies might develop."[481]

Shortly after that innovation, another research team announced that it had discovered a method for transferring a selected protein from variola into vaccinia, thereby making the recipient virus one hundred times more infective than the original, and explaining how that particular protein is responsible for variola's unique ability to defeat the human immune system.[482] Again, the technology offers benign applications (it may eventually lead to advances in anti-smallpox pharmaceuticals), but the potential for abuse is also manifest.[483]

These salient technological breakthroughs have also provoked a political response: some have staunchly opposed publication of such lurid results, arguing that the innovations can be abused by terrorists or rogue militaries, co-opting the pure science insights for hostile applications.[484] The notion of classification, self-censorship, or otherwise restricting publication of "contentious research" has been asserted anew, but advocates of the free flow of scientific information have again rallied to defend an open marketplace of ideas, even in the era of terrorism.[485]

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481. INST. OF MED., *supra* note 170 at 64-67; *see also* Michael Balter, *On the Trail of Ebola and Marburg Viruses*, 290 SCI. 923, 925 (2000) (reporting that researchers have constructed a DNA molecule complementary to that of the Ebola virus and used it in cultured cells to produce Ebola RNA, thus concocting an infectious laboratory-created virus); Check, *supra* note 477 (noting Eckard Wimmer's comment that now "You cannot eliminate a virus from existence"); Rick Weiss, *Genetic Find Could Lead to Creation of Life from Scratch in Lab*, WASH. POST, Dec. 10, 1999, at A8 (explaining that "new research may enable scientists to engineer life in the laboratory for the first time from essential chemical ingredients—not by altering existing organisms, as genetic engineers do today").

482. Ariella M. Rosengard et al., *Variola Virus Immune Evasion Design: Expression of a Highly Efficient Inhibitor of Human Complement*, 99 PROC. NAT'L ACAD. SCI. 8808 (2002) (discussing how disabling the smallpox inhibitor of complement enzymes (SPICE) "may be therapeutically useful if smallpox reemerges").

483. Schemo, *Sept. 11 Strikes*, *supra* note 462 (appraising the effect of new rules that govern biological research).

484. *See* Couzin, *supra* note 355, at 749 (stating that members of Congress introduced a resolution opposing publication of unclassified scientific data that could be of use to terrorists); Check, *supra* note 477, at 265 (reporting that restrictions may be placed on scientific publications for fear that they will be used by terrorists).

485. *See* Bruce Alberts & Robert M. May, *Scientist Support for Biological Weapons Controls*, 298 SCI. 1135 (2002) (stating that advances in science, facilitated by open publication, can help decrease the threat of biological warfare by improving treatments); Gerald Epstein, *Controlling Biological Warfare Threats: Resolving Potential Tensions among the Research Community, Industry, and the National Security Community*, 27 CRITICAL REV. MICROBIOLOGY 321, 335-36 (2001); P.J. Lachmann, *Microbial Subversion of the Immune Response*, 99 PROC. NAT'L ACAD.

In any event, two basic conclusions seem apt for future smallpox-related inquiries. First, we can never predict when, where, or in what direction future technological breakthroughs will occur. Scientific inquiries simply do not follow the timetables established by politicians or comptrollers, nor do they adhere to a hope for exclusively peaceful advantages. No matter how earnestly we seek a solution, and no matter how much money we throw at the problem, success is never guaranteed. Second, we will literally never exhaust all that variola might be able to teach us. Even if our current techniques, equipment, and conceptual models run through their entire repertoire of currently contemplated experiments, it is certain that future generations of investigators, armed with enhanced tools and ideas, would be able to ask questions of variola, and divine useful answers, that are beyond contemporary ken. So the process of plumbing variola's mysteries, and discerning their applicability to other virology and immunology conundrums, may literally never be completed.

V. RECOMMENDATIONS

What, then, should we do about this array of public policy dilemmas? This section offers recommendations in six areas, drawing upon each of the three strands of public policy identified above.

A. *Retain the Variola Virus Samples*

First, we should decide now to retain the remaining variola virus samples indefinitely—essentially forever. Admittedly, the symbolic value of complete eradication (originally of the disease, and now of the causative virus) would be satisfying—nothing is so conclusive or triumphant as permanent extermination of a hostile species. But that cathartic gain is simply not worth what we would be losing by foregoing forever access to this unique genetic entity. There is still much we can learn from variola. It is a unique creature, one that has so closely accompanied human beings for millennia, and it has waged a battle against us more skillfully than any other microorganism. Instead of throwing it away, we should now follow Ovid's advice that we can learn even from our worst enemies.[486]

SCI. 8461, 8462 (2002) (arguing that inquiries like the variola-vaccinia gene transfer are much more likely to assist in combating disease than in promoting terrorism); Schemo, *Sept. 11 Strikes*, *supra* note 462 (reporting that government regulations "threaten to undermine the fundamental openness of science and campus life").

486. OVID, *The Story of Athamas and Ino*, *in* METAMORPHOSES 94, 95 (Rolfe Humphries trans., 1955) (stating "to learn from enemies is right and proper").

I also recommend abandoning once and for all the pretense that what is at stake is only the "temporary" retention of the samples frozen in the CDC and Vector laboratories. The smallpox saga is littered with the WHO's missed deadlines for eradicating the species; on each occasion when the virus truly seemed poised on the world's chopping block, the organization has blinked, backed off, and then set another unwittingly false execution date.[487] It serves no purpose to continue the charade of "final" deadlines; let us admit frankly that permanent retention is appropriate.

Just as absurd is the current U.S. position that eradication could be undertaken as soon as the list of five new research objectives is met.[488] Like Louis Carrol's White Queen, who struggled to believe six impossible things before breakfast,[489] the American proponents have advanced such an ambitious and rather arbitrary set of objectives, establishing unnecessarily arduous research goals, that the strategy can only be understood as a thin veneer for permanent retention. Rather than pretending to cling to that fixed agenda, we should now overtly resolve to unlink the research protocol from the question of perpetuation of the CDC and Vector repositories.

B. Produce More Vaccine, but Not 300 Million Doses

The United States and the entire world were long overdue for a resumption of smallpox vaccine production. The global inventory had fallen far too low; years of neglect and disinvestment caused the known, viable stockpile to dwindle to unacceptable levels.[490] The pre-September 11 recommendation of the Working Group on Civilian Biodefense for a U.S. supply of 40 million doses[491] was about right, if somewhat on the conservative side. Subsequent initiatives by the Departments of Defense and Health and Human Services would have built up to that level. Initially, this would have been accomplished rather slowly, but the schedule has subsequently been accelerated.

The adventures in over-contracting since that time have illustrated, however, that no idea is so good, no undertaking so valuable, that it cannot be wildly overdone. America does not need 300 million

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487. *See supra* notes 160-167 and accompanying text (describing previous failures to follow variola extermination dates).

488. *See supra* text accompanying note 388 (setting forth five criteria that must be met before destroying variola samples).

489. LEWIS CARROLL, THE COMPLETE ALICE & THE HUNTING OF THE SNARK 188 (2d ed., Salem House Publishers 1987) (1865).

490. *See supra* notes 147-153 and accompanying text (describing the amount of vaccine available to the WHO to combat smallpox infections after 1980).

491. *See* Henderson et al., *supra* note 43, at 2136.

vaccinia doses. We would never administer that many, and it is irresponsible to propound the view that sheer wastage of hundreds of millions of dollars in that way constitutes a valuable national "insurance policy." And now, the combination of a newfound ability to dilute the existing vaccine supply,[492] with the belated discovery of the buried treasure of an additional 85 million doses (probably also subject to one-to-five dilution) donated by its manufacturer,[493] affords us vastly more of the stuff than we could use.

At this point, it is simply wasteful to procure so much smallpox vaccine and to create additional structures for administering it when there are so many other health care and national security priorities still unmet. Hospitals, state health agencies, and other institutions are diverting funding and attention from other pressing needs—influenza, for example, kills ten thousand or more Americans every year—to perfect our defenses against a threat that is still described as remote.[494]

In reality, if there ever were a smallpox outbreak, caused by any plausible scenario of accidents, terrorism, or wartime use, we would not vaccinate everyone in America. Doing so in an era of so many immunosuppressed people and others with significant contraindications would injure and kill more citizens than the virus itself.[495] Instead, we would rely upon the same methodology that conquered smallpox around the world during the ISEP: rigorous surveillance to identify promptly any emergent cases, followed by containment, via urgent vaccination of anyone in the vicinity of a known case, or anyone who might have incurred even indirect exposure to the virus.[496] A larger vaccination effort, if the initial attack were robust enough to outrun the containment strategy, could be undertaken later, as needed.[497]

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492. LeDuc et al., *supra* note 470, at 743 (stating that Dryvax vaccine remains potent and effective even when diluted to 1/5 or even 1/10 of its original strength).

493. Connolly, *supra* note 407 (reporting that Aventis Pasteur will donate 85 million does of smallpox vaccine); Stevenson & Stolberg, *supra* note 91.

494. Ceci Connolly, *Bush Plan for Smallpox Vaccine Raises Medical, Fiscal Worries*, WASH. POST, Dec. 15, 2002, at A33 (reporting the view of William Schaftner, chairman of preventative medicine at Vanderbilt University Medical Center).

495. Thomas Mack, *A Different View of Smallpox and Vaccination*, 348 NEW ENG. J. MED. 460, 462 (2003) (stating that more than 800 deaths may occur from complications if the entire U.S. population was vaccinated).

496. *See supra* notes 116-120 and accompanying text (describing the development of the surveillance-containment method and its role in the ISEP).

497. Although each situation is, of course unique, some lessons can be derived from one of the last outbreaks of smallpox in the United States. In 1947, a man infected in Mexico imported the disease to New York, where he died in a Manhattan hospital, with the misdiagnosis of acute bronchitis. The correct assessment was not made until other cases of

To ensure the success of that type of program, we will need to upgrade the existing public health infrastructure in the United States and elsewhere—another overdue investment we should be making anyway. The institutional and personal mechanisms for timely detection of unusual diseases, for accurate diagnosis of them, and for dissemination and administration of the necessary treatments, are archaic and in disrepair.[498] Capabilities for speedy communications between health officials at different federal, state, and local service providers have not kept pace with modern technology, nor with the demands of an increasingly mobile population. Doctors and other health professionals have not been trained to recognize smallpox, and might not quickly or reliably appreciate its signs and symptoms, unless tipped off by other sources.[499] All of that must be fixed, and it should not have required the upheavals of September and October 2001 to sensitize us to that imperative.

When the massive new smallpox vaccine inventory becomes available, it should be housed in secure, reliably climate-controlled facilities—*not* administered to the general public. Beyond selected military personnel, primary health professionals, and other "first responders" who might be placed at unusual risk, the general civilian population should not be vaccinated, even if some of them affirmatively seek the injection. The risks are simply too great: a nationwide program of vaccination today would result in hundreds of deaths, thousands of serious illnesses, and countless days lost from work and military service—all at a time when no one in the United States has contracted smallpox in over fifty years.[500] Moreover, anyone who does receive the vaccine becomes temporarily contagious with its vaccinia virus. While that contagion is relatively mild for most people, it presents a

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smallpox arose in people who had contact with him in the hospital, and eventually twelve people were infected, of whom two died. In the associated panic, some six million New Yorkers were vaccinated (more than half of them within a month). Six people died from complications of the vaccine. FENNER ET AL., *supra* note 14, at 331-32; HOPKINS, *supra* note 43, at 293-94; Jimmy Breslin, *Saving Public from the Pox*, NEWSDAY, Nov. 19, 2002, at A4; *see also* Mack, *supra* note 495, at 462 (arguing for a step-by-step approach, vaccinating additional groups of people only after we see how well the early rounds succeed).

498. *See* Foege, *supra* note 431 (proposing the following preparations to combat widespread smallpox infection: "getting needed supplies in place . . . training volunteers, National Guard and public health workers how to vaccinate with bifurcated needles . . . strengthening public health infrastructure . . . shipping vaccines nationwide overnight . . . holding clinics in every high school").

499. Ceci Connolly, *For Thompson and HHS, A 'Heightened Awareness'; Response to Attacks Is Both Immediate and Long-Term*, WASH. POST, Oct. 30, 2001, at A29 (quoting a surgeon stating that, "I've never seen a case of anthrax or smallpox" and emphasizing the importance of training health professionals to recognize these diseases).

500. Delthia Ricks, *1st Shot for Smallpox Vaccine*, NEWSDAY, Jan. 31, 2003, at A43.

potentially lethal hazard for others who might be casually and unknowingly exposed in ordinary daily activities.[501]

Unless the threat of a smallpox attack suddenly appears to be much more imminent, which the U.S. leadership has repeatedly asserted is not the case at the moment, this remains a situation in which the duty of the government is to reassure a skittish public, not to hype the threat of smallpox bioterrorism. The government should continue to withhold a treatment regimen that might initially appear to be "erring on the safe side," but is, instead, simply erring.[502]

C. *Pursue Improved Bio-Detectors*

One of the top priorities for the research agenda—affirmed by the 1999 IOM study, by the subsequent WHO authorization for an interim work program, and most recently by the Bush administration—is improved detectors.[503] These would seek both more rapid and certain diagnosis of smallpox in a human body, and an enhanced capacity for discriminating variola particles in the environment, where a terrorist or aggressive military force might spew biological weapons.[504]

This is one of the few areas where the research protocol aims at an objective that is not only important, but achievable in the near term. Moreover, it is also a topic for which perpetual access to live, intact variola (and the concomitant requirement that the research be conducted only within the shelter of high-containment BL-4 facili-

501. Ironically, programs advocating early vaccination of primary health care workers, who would contribute to the first response to a potential smallpox outbreak, might exacerbate this danger. Unless quarantined for days or even weeks after vaccination, these health professionals would run the greatest risk of passing the vaccinia virus to their current patients, who might be among the most vulnerable populations. Kemper & Mestel, *supra* note 431.

502. Foege, *supra* note 431 (stating that the American public "should take comfort from Bush's reassurance that the [smallpox] threat is not imminent"); *see also* Kemper & Mestel, *supra* note 431 (reporting the concern of Dr. George E. Hardy, executive director of the Association of State and Territorial Health Officials, that the cost of a vigorous smallpox vaccination campaign should not come at the expense of other public health programs).

503. *See* INST. OF MED., *supra* note 170, at 59-62 (explaining that studying ways to detect smallpox is a compelling reason not to eradicate the variola virus); *U.S. Opts to Keep Smallpox Stock*, VACCINE WEEKLY, Dec. 12, 2001, at 2.

504. *See* U.S. ARMY SOLDIER & BIOLOGICAL CHEMICAL COMMAND, HISTORY OF CHEMICAL AND BIOLOGICAL DETECTORS, ALARMS, AND WARNING SYSTEMS 35 (Kathleen S. Ciolfi, ed. (undated)) (describing a laser than can detect biological aerosol clouds up to five kilometers away).

ties)[505] might be unnecessary. Manipulating selected distinctive non-infective fragments of the virus should suffice for many purposes.

In recent years, the U.S. military has experimented with, developed, and sought to deploy a range of broad-spectrum bio-detectors, each of which has suffered from high cost, limited range of operation, restrictions in the number of pathogens it can identify, and lack of battlefield hardiness.[506] Improvements, however, may be about to cascade into availability, and they could offer commanders a vastly improved ability for tactical warning about oncoming smallpox and other BW.[507]

This sector, therefore, is one of the most promising research avenues, and it should be vigorously pursued, for applications in civilian, urban anti-terrorism operations (such as at stadiums, subways, or office buildings), as well as on the organized battlefield. Accompanying it ought to be additional training for the first responders, who would have to know how to operate and maintain the equipment, what to do with the information they were receiving from it, and how to deal on an immediate basis with the emerging biological threats.

D. *Pursue Broad Variola Research, but More Skeptically*

If we could somehow suddenly get our hands on a new family of broad-spectrum (or even variola-specific) antivirals and a safer, equally effective vaccine, that would be wonderful, but magic is unlikely to come to our assistance in that way, and step-by-step basic research in those directions will not be cheap, easy, quick, or certain to pay off.

Moreover, variola poses persistent special problems to researchers. The lethality of the disease forbids reliance upon the usual array of required testing algorithms.[508] We cannot casually administer test

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505. *Bush Proposes Major Raise for NIH, Including $1.5 Billion in Bioterror Research,* VACCINE WKLY, Feb. 13, 2002, at 10.

506. MILLER ET AL., *supra* note 203, at 106-07, 120, 283-84 (describing problems with biodetectors); U.S. ARMY SOLDIER & BIOLOGICAL CHEMICAL COMMAND, *supra* note 504, 13-35 (tracing the development of biological agent detectors and describing how they function).

507. Rocco Casagrande, *Technology Against Terror,* 287 SCI. AM. 83 (Oct. 2002) (identifying current biodetectors); Laurie Garrett, *The Nightmare of Bioterrorism,* 80 FOREIGN AFF. 76, 83-84 (2001) (discussing federal funding of biosensor research); Gary Stix, *The Universal Biosensor,* 287 SCI. AM. 37 (2002) (describing the development of a new biosensor, TIGER (triangulation identification for genetic evaluation of risks), that can detect bacterium, virus, fungus, or protozoan); William J. Broad, *Arms Inspectors in Iraq to Deploy New Technology,* N.Y. TIMES, Nov. 13, 2002, at A1 (discussing new warfare and antiterrorism technology).

508. *See* Zoon, *supra* note 379, at 535 (explaining that test doses are not possible because they would subject healthy humans to a lethal or permanently disabling agent).

doses of new pharmaceuticals in controlled experiments to informed volunteers and challenge them with the deadly, intact smallpox virus to determine whether we have properly conceived a useable new medicine.[509] The Food and Drug Administration will have to demonstrate unusual flexibility and creativity, therefore, to validate any new anti-variola preparations through extended trials in cell cultures and newly crafted animal models.

Additionally, the inescapable hazards of the subject mandate that much of the investigatory work can be conducted only in the world's precious few BL-4 facilities, where it will inevitably compete with other pressing research programs, some of which ought properly to be accorded an even higher priority. As great as the terrorist threat of smallpox might be, after all, AIDS, Ebola, West Nile, dengue fever, and a host of other viruses are *current*, not merely potential, killers of human beings.

Moreover, it must be recalled that the probability is low that we would ever want to administer even a new, improved vaccine to massive numbers of people. The likelihood of a new smallpox outbreak is still quite remote (for all we know), and the surveillance-containment strategy should (as it did during ISEP) obviate the necessity for universal vaccination. Likewise with an antiviral medication: it would surely be handy to have such a treatment available in case of a smallpox outbreak, but it is not absolutely essential. Instead, we would rely upon vaccination, which can effectively ward off the disease even if administered as late as four days after the person is exposed to variola.[510] Therefore only the earliest victims—those who fell ill before the disease was recognized as smallpox and the vaccination response was initiated—would rely solely upon *post hoc* antiviral treatment.[511] That category could encompass many people, depending upon the scenario one has in mind, but it is not infinitely large. It is, therefore, not worth devoting an unending stream of research dollars and displacing valid research on other life-saving programs in its pursuit.

E. Pursue Other Basic and Related Research More Directly

Among the most tantalizing hopes for a successful variola research program would be its potential applicability to other medical

509. *Id.*

510. D.A. HENDERSON, THE RESEARCH AGENDA UTILIZING VARIOLA VIRUS: A PUBLIC HEALTH PERSPECTIVE (WHO Comm. Mtg. on Research, Working Paper 1999), *available at* http://www.hopkins-biodefense.org/pages/agents/research.html (last visited Apr. 10, 2003).

511. *Id.*

and biological sectors. Our explorations of smallpox may spawn diverse insights materially assisting in the battle against other stubborn viral and bacterial agents.[512] More generally, enhanced understanding of the variola infection process may elucidate some of the many mysteries of the human immune system; for example, some researchers suggest that the program may generate nuances about the phenomenon of the human body's problematic rejection of organ transplants.[513]

All those future applications would surely be desirable, and the possibility of realizing them must be factored into decisions about how much and what types of variola research to undertake. But surely the wiser national strategy would be to approach those other desiderata directly, rather than through the filter of smallpox. That is, if we seek to learn more about other viral diseases, let us study them. If the objective is to improve our understanding of immunology or organ transplants,[514] we must devote the necessary resources directly to those issues, rather than hope that appropriate insights will serendipitously emerge from a research program that is focused on other objectives and driven by other goals.

There are so many threatening microorganisms in the world today, and rapacious new diseases seem to be emerging with such stunning regularity,[515] that a concerted national and international health strategy is needed to combat them. The priorities among competing research opportunities ought to be decided on a coherent, comprehensive basis, rather than just hoping that smallpox inquiries—which may jump to the head of the funding queue for external, political reasons—can be justified on this wider rationale.

In any event, additional resources will be required. One vivid illustration of the current paucity is the scarcity of BL-4 laboratory suites and related hospitalization facilities.[516] These institutions are expensive to construct and demanding to maintain, and the hazards

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512. *See* Joklik et al., *supra* note 168, at 1226.

513. *Id.*

514. *See* Barbara Hatch Rosenberg, *Anthrax Effects Still Troublesome*, NEWSDAY, Sept. 24, 2002, at A27 (arguing that the United States should devote resources to the public health system, rather than to biological weapons agents).

515. *See* Denise Grady, *Managing Planet Earth, On an Altered Planet, New Diseases Emerge as Old Ones Re-emerge*, N.Y. TIMES, Aug. 20, 2002, at F2 (noting that since the mid 1970s, a new array of previously unknown diseases has arisen).

516. *See* Rex Dalton, *Residents Force Review of Biodefence Lab*, 419 NATURE 423, 423 (2002) (explaining that the only large BL-4 labs in the United States are located at the CDC in Georgia and at Fort Detrick in Maryland).

they contain will inspire NIMBY-related neighborhood opposition.[517] But they constitute a vital component in a rational research strategy. The only way to conduct the quantities of cutting edge research we need—for smallpox and other related viruses, or diverse health threats more generally—will be to expand the availability of these premium facilities.[518]

Physical security, too, is an essential component—for the existing WHO Collaborating Centers in Atlanta and Koltsovo, as well as for any other institutions that may touch biological disease agents. These days, it is commonplace to suggest that anti-terrorism protections must be enhanced.[519] Although this modern threat is surely staggering, it is only one kind of danger, and not necessarily the most probable. Industrial accidents happen at even excellent facilities;[520] spies still seem to lurk everywhere;[521] disgruntled employees can create havoc in endless ways. Georgia and Novosibirsk certainly have their share of natural disasters: hurricanes, earthquakes, fires, and floods occur everywhere, without much warning. The busy Hartsfield International Airport is only a few miles from the CDC Atlanta headquarters.

All of this is not to suggest that the sky is falling; both the CDC and Vector have recently been certified by the WHO as incorporating adequately stringent physical security protections surrounding their precious variola stocks.[522] But we cannot become complacent. The reality these days is that security is an ongoing process, and the protections must be constantly reviewed and the routines frequently varied, to stay one step ahead of the emerging dangers.

F. Fight Global Terrorism in Other Ways

The challenge of modern super-terrorism demands a diverse, multi-faceted response. The front lines of the battle will depend initially on improved, and sometimes unconventional, military capabili-

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517. *See id.* (explaining that these facilities must be developed in collaboration with communities because of potential injuries and the environmental impact of the facilities).

518. *See id.* (neighborhood opposition has delayed efforts to build a BL-4 complex in Hamilton, Montana).

519. *See, e.g.*, Connolly, *supra* note 140 (explaining that with the recent threats of biological attack, Jeffrey Koplan said "the CDC needs to tighten security and enhance lab capacity").

520. *See* Weiss & Snyder, *supra* note 141 (discussing an accidental release of anthrax spores at Fort Detrick).

521. Pincus, *supra* note 173 (reporting on the flourishing spy business).

522. World Health Organization, Report by the Secretariat, Smallpox Eradication: Temporary Retention of Variola Virus Stocks (2000), A53/27.

ties; on enhanced intelligence operations, to collect warning data and conduct better threat assessments; and on skillful diplomacy, to rally the world community to the cause and deter other states from assisting or harboring terrorists.

Law can also play a role here, specifically international law regarding anti-terrorism and biological weapons, and the BWC should be the centerpiece of the effort. The United States should take the lead in enhancing that treaty, not in undercutting it. If the 2001 draft protocol was deficient,[523] the proper place for America is out in front, working to develop better concepts and mutually acceptable language to accomplish the difficult goals, not lagging behind and dragging our feet. The current posture exhibits the worst forms of unilateralism: The United States expects the rest of the world to rally behind us in the struggle against international terrorism in our time of great need, but we have so far been unwilling to demonstrate the requisite good faith to craft a workable, broadly acceptable solution for a document that could, if America demonstrates a bit more flexibility and a good bit more effort, materially assist the joint enterprise.

Of course, even an amended BWC, by itself, could tackle only a small portion of the overall problem. Other accords and strategies will be necessary to cut off terrorists' access to their traditional funding sources, to interdict their supply of weapons, and to impinge upon their travel and communications. But an enhanced BWC could become a useful tool. It could drive the countries to make the pursuit of BW by rogue states and terrorists appreciably more cumbersome and time-consuming.[524] It could enhance countries' confidence that their treaty partners were reliably abandoning offensive biological operations, making it safer for them to adhere to the same path. The negotiations surrounding a BWC protocol could also become a focus for other efforts—for example, the idea of making bioterrorism an international crime,[525] subject to prosecution in a new international tribunal or (through the concept of "universal jurisdiction") in the

523. David P. Fidler, *Bioterrorism, Public Health, and International Law*, 3 CHI. J. INT'L L. 7, 13-14 (2002) (critiquing the 2001 draft protocol).

524. *See id.* at 14 (arguing that the immediate adoption of a BWC protocol would reduce the threat of biological weapons proliferation and bioterrorism).

525. See Michael Barletta et al., *Keeping Track of Anthrax: The Case for a Biosecurity Convention*, BULL. ATOMIC SCIENTISTS, May/June 2002, at 57 (discussing some of the ideas from the fifth BWC review conference, including urging treaty members to criminalize the possession and use of bioweapons).

national judicial system of any country that could get its hands on the perpetrator.[526]

Most of all, the United States should follow a version of the Hippocratic Oath: whatever we do to combat biological warfare and bioterrorism, we should avoid making the situation worse. American policy has not always heeded that wise, if basic, injunction. Our unilateralist approach to the BWC disregards the sensitivities, the interests, and the potential contributions of other countries, driving them away from collaboration with us, instead of seeking areas of accord.

For example, it was revealed in September 2001 that the United States had sustained a program of evading, if not quite violating, the BWC by covertly acquiring biological weapons-related materials on the international black market, and testing them to discern their capabilities and to divine strategies for negating them.[527] In addition, the United States had constructed, in a secret location in the Nevada desert, a prototype, non-functional biological weapons factory, purportedly to demonstrate how easy it would be for terrorists or rogue states to acquire indigenous BW capability by purchasing dual-capable equipment and materials on the open market.[528] While these efforts may have had entirely legitimate and salutary objectives, they certainly came close to violations of the BWC and the United States surely would have protested mightily if any other country had secretly undertaken to skate so close to the edge of the treaty. Demonstrations of that sort, manifesting a disregard for the most important treaty in the field and a lack of concern for the opinions of our partner states, do not assist the effort to rally the world community against bioterrorism.[529]

In addition, the United States should be much more attentive to the perhaps fleeting opportunity to assist in Russia's demilitarization

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526. Every state has the authority to inflict punishment for selected categories of crimes recognized by the community of nations as being offenses of global concern, regardless of any specific connection to that state. RESTATEMENT OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES § 404 (1986). Traditionally, only a few egregious activities (e.g., piracy, slavery, genocide) were recognized as legitimate topics of this universal jurisdiction, but the category is growing to embrace, for example, war crimes and aircraft hijacking. *Id.* cmt. a.

527. Rosenberg, *supra* note 514 (explaining that other countries have voiced concerns over secret U.S. biodefense projects that "push against the limits of international prohibitions").

528. *See* MILLER ET AL., *supra* note 203, at 297-99; Vernon Loeb, *U.S. Seeks Duplicate of Russian Anthrax*, WASH. POST, Sept. 5, 2001, at A16.

529. *See* MILLER ET AL., *supra* note 203, at 296-310 (discussing the United States's secret programs to develop ostensibly defensive tools to combat BW and CW, and the potentially threatening impact of that work on other nations); Loeb, *supra* note 528.

program, beginning with Vector and the rest of Biopreparat. For a decade, the United States has allocated modest sums through the Nunn-Lugar and other threat reduction programs,[530] to facilitate Moscow's efforts to account properly for all the weapons of mass destruction produced in the Soviet era, to rein in those materials and facilities under adequate security, and to begin the laborious and expensive process of destroying them or converting them to peaceful applications.[531] That is a wonderful idea—a genuine win/win solution—resulting in peacefully promoting an objective that obsessed the United States throughout the cold war era: how to reduce the threat that Soviet nuclear, biological, chemical, and other weapons pose to our homeland. We have, through quite paltry U.S. contributions, supported the dismantling of far more weapons than earlier generations of our generals and diplomats could have imagined, all without firing a shot.

The time has come to accelerate that program, even as the current U.S. leadership seems to be backing away from it.[532] Biological weaponry offers a particularly propitious opportunity: the facilities and the personnel that formerly masterminded the Soviet BW program should have ample scope for conversion into peaceful civilian applications. If catalyzed by Western capital, management advice, and other support, the Biopreparat apparatus should be transformed into a home for profitable and benign pharmaceutical, agricultural, and industrial research and production.[533]

Vector has already undertaken important steps in this direction, yanking itself from the Soviet weapons programs into the modern world economy.[534] Much more could be done in this vein to help

530. Press Release, Federation of American Scientists, United States and Russia Extend Nunn-Lugar Cooperative Threat Reduction Agreement (June 24, 1999), *available at* http://www.fas.org/nuke/control/ctr/news/b06241999_bt307-99.htm (visited Apr. 10, 2003).

531. *Id.*

532. Christine Kucia, *Congress Gives Bush Three-Year Waiver for Threat Reduction*, ARMS CONTROL TODAY, Dec. 2002, at 24; Richard G. Lugar, *The Next Steps in U.S. Nonproliferation Policy*, ARMS CONTROL TODAY, Dec. 2002, at 3 (recounting efforts to obtain legislative authority to waive stringent limitations placed on assistance to Russian weapons dismantling programs); Editorial, *Safeguarding Soviet Weapons*, N.Y. TIMES, July 26, 2002, at A32 (reporting that the Bush administration is internally divided about continuing assistance to Russia for weapons dismantling).

533. *See* U.S. GEN. ACCOUNTING OFFICE, GAO/NSIAD-00-138, BIOLOGICAL WEAPONS: EFFORT TO REDUCE FORMER SOVIET THREAT OFFERS BENEFITS, POSES NEW RISKS 4-6 (2000) (explaining that the U.S. strategy for addressing proliferation threats has been to fund research activities that increase the Russian institutes' openness to the West and redirect scientists toward peaceful civilian research).

534. *See* Ken Alibek & Stephen Handelman, *Don't Give Russia the Smallpox Franchise*, PLAIN DEALER, May 26, 1999, at 11B (explaining that Vector has ended its military function

other Russian sites ensure that the conversion to civilian activities is irreversible and that the key scientists and other alumnae of the military operations find sufficiently remunerative opportunities in peaceful enterprise so that the apparition of brain drain to hostile states and applications is avoided. It would not require very much U.S. money to help make all that happen, but it would require some. Moreover, a more constant approach and a commitment to genuine, enduring leadership in facilitating the transformation are required, guided by an appreciation for true, long-term U.S. and global interests.

Finally, we need to re-examine security standards across the board, beginning with fresh appraisal of the mechanisms at the CDC and Vector, and especially with tightening the general access to dangerous pathogens.[535] The new U.S. legislation has initiated the process, restricting—but not rigidly over-restricting—who can obtain which of the most dangerous potential BW substances, for what purposes, and pursuant to what safety strictures.[536] This is another area where international cooperation is essential: there are hundreds of germ banks around the world that observe radically different standards regarding sales of even the most lethal substances.[537]

CONCLUSION

Regarding retention or destruction of the smallpox virus, the current United States posture is doing approximately the right thing, but for many of the wrong reasons. We should, at the bottom line, preserve those last frozen exemplars of variola, and should undertake an orderly, substantial program of long-term research on its microscopic operations and on possible ameliorative pharmaceuticals. We should, however, overtly commit to preserving this unique viral resource permanently, not setting yet another unrealistic deadline, and not pur-

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and the United States is encouraging its scientists to make the transition to peaceful research).

535. *Russia, Iraq and Other Potential Sources of Anthrax, Smallpox and Other Bioterrorist Weapons, Hearing before the House Committee on International Relations*, 107th Cong. 20 (Dec. 5, 2001) (testimony of Elisa D. Harris, Research Fellow for International and Security Studies).

536. *Id.*

537. Michael Barletta et al., *Keeping Track of Anthrax: The Case for a Biosecurity Convention*, BULL. ATOMIC SCIENTISTS, May/June 2002, at 57; Rick Weiss, *Ordering Germs? There Are Hurdles First*, WASH. POST, Oct. 12, 2001, at A27.

porting to tie the destruction timetable to implausible short-term research successes.[538]

Here, however, the current U.S. approach seems unnecessarily and unwisely driven by misbegotten military objectives, which should properly play only a relatively minor role in the drama. That is, even if rogue states or terrorists were known to have preserved their own secret stashes of variola, that deceit by itself would not be a sufficient reason for the United States to cling to the CDC inventory. After all, we would never retaliate *in kind* for a variola attack, even if we knew for certain who had launched it.[539] We would respond, instead, with the full panoply of conventional military and diplomatic tools at our disposal—but the United States rightly foreswore offensive biological warfare and jettisoned its capacity for that kind of combat three decades ago.

The United States does not require perpetual access to live variola in order to upgrade most of our defenses against its possible use. Intelligence, diplomacy, conventional military operations, and the domestic public health infrastructure can be enhanced without it; these will constitute our real protection against a revival of smallpox. For some important purposes, such as developing improved bio-detectors, enhanced antiviral medications, and safer vaccines, research building upon the intact virus is still required, but we should not over-state how urgent those needs are, or how soon we might accomplish the desired breakthroughs.

Moreover, by doing the right thing for the wrong reasons, the United States may make the current security situation appreciably worse. For example, if we continually demonstrate unilateralist disrespect for the BWC[540] and for the other sovereign states that have been struggling against long odds to improve it; if we communicate to foreign governments that we are perpetuating our own covert BW-related programs, sliding right up to the line of activities banned by the treaty;[541] and if we enable the suspicious among them to harbor conspiracy theories that the United States has, in fact, retained an interest

538. *See* Joklik et al., *supra* note 168, at 1226 (explaining the importance of increased effort to understand the disease).

539. *See* Stephanie A. Powell, *U.S. Diplomacy and the Future of the BWC*, ARMS CONTROL ADVISORY (2002), *available at* http://www.lawscns.org/media/acadvisory/ACAdvisory012402BWC.html (last visited Apr. 10, 2003).

540. *See* Powell, *supra* note 539 (noting that at the last BWC conference, the U.S. indicated its preference for a unilateral approach to BWC verification and its unwillingness to engage in the formal treaty-negotiating process), *available at* http://www.lawscns.org/media/acadvisory/ACAdvisory012402BWC.html.

541. *See* Rosenberg, *supra* note 514.

in an offensive BW program of its own, then surely we will have undercut our true objectives. Furthermore, if we advertise to other countries and to non-state actors that bioterrorism (and especially smallpox) is the sort of attack we fear the most, and are most vulnerable to, will that not inspire them to proceed further in those noxious directions?

In so many ways, the United States and the world have progressed well beyond the standards of 1973. In security, health, technology, and many other sectors, we have succeeded in exploiting and refining the innovations that first reared their heads in that most pathbreaking year. The intervening period has witnessed the revolutions in genetic engineering, promising the ability to manipulate the natural world in breathtaking ways; the culmination of the global campaign against smallpox, the first, and still the only, disease that the world has ever managed to eradicate; and the achievement of the Biological Weapons Convention, the first genuine measure of true disarmament in the modern era.

The question now is whether we will continue to be the masters of those diverse, and now inextricably inter-related, areas of public policy, or whether the sheer complexity of the issues and the difficulty of sorting through the permutations they offer will instead empower the problems to propel us blindly forward.